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

Last Approval: 12/11/2024
Next Review Due By: December 2025

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

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 resource 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.

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

Gilligan et al. (2023, 2021) conducted a randomized controlled trial (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.

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

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. 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

Gilmore et al. (2023) conducted a prospective, multi-center case series to explore the lasting effects of medial branch peripheral nerve stimulation (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.

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 evaluates 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** (APSN, (Strand et al. 2022) published evidence-based guidelines for the use of implantable peripheral nerve stimulation to treat chronic pain. The best practice guidelines were as follows:

"Upper Extremities: PNS may offer modest and short-term pain relief, improved physical function, and better quality of life for chronic hemiplegic shoulder pain. LoE II-3, Grade B.
PNS for mononeuropathies of the upper extremity may be offered following a positive diagnostic ultrasound-guided nerve block of the targeted nerve and is associated with modest to moderate pain relief. LoE II-2, Grade B.

Low Back/Trunk: 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. LoE I, Grade B.
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. LoE II-2, Grade B.
There is limited evidence that PNS may alleviate pain in neuropathic pain syndrome involving the trunk and back including radiculopathy and post-herpetic neuralgia. LoE III, Grade C.

Lower Extremities: PNS may be considered for lower extremity neuropathic pain following failure of conservative treatment options and is associated with modest pain relief. LoE I, Grade B.
PNS may be considered for lower extremity post-amputation pain following failure of conservative treatment options and is associated with modest to moderate pain relief. LoE I, Grade B.

Other Considerations: 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. LoE III, Grade C

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."

The **International Neuromodulation Society** published a Neuromodulation Appropriateness Consensus safety guideline stating the following recommendations (Deer et al. 2017):

"PNS has not been associated with direct neurologic trauma and its risk is low. LoE II-3, Grade B.

Imaging guidance, as well as intermittent nerve stimulation, is recommended for percutaneous PNS placement. LoE II, Grade I.

Specialized equipment designed for PNS will likely improve efficacy, safety, and reduce complication rates. LoE III, Grade B."

The **National Institute for Health and Care Excellence (NICE)**

In its 2022 guidance on interventional procedures for neurostimulation of lumbar muscles for refractory non-specific chronic low back pain, NICE found that the evidence regarding the effectiveness and safety of neurostimulation for lumbar muscles in cases of refractory, non-specific chronic low back pain is not abundant or robust. Therefore, the guideline advises that this procedure should only be conducted under specific clinical governance, with proper consent and monitoring or as part of research studies.

NICE published an interventional procedures guidance (2013) on peripheral nerve field stimulation for chronic low back pain. The evidence-based guidance concluded peripheral nerve-field stimulation that involves implanting electrodes in the back, connected to a neurostimulator under the skin to mask the back pain by modulating the transmission of pain signals to the brain, does not have sufficient evidence lending to its safety and efficacy. As the evidence is lacking in both quality and quantity, the NICE urges physicians implementing this technology to do so in special patient cases after conferring with a multidisciplinary team.

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]

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	Adaptor/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, 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

12/11/2024 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.

REFERENCES

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database: National coverage determination – electrical nerve stimulators (160.7). Effective August 07, 1995. Accessed November 19, 2024. https://www.cms.gov/medicare-coverage-database/search.aspx
2. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database: National coverage determination – assessing patient's suitability for electrical nerve stimulation therapy (160.7.1). Effective June 19, 2006. Accessed November 19, 2024. https://www.cms.gov/medicare-coverage-database/search.aspx
3. Deer TR, Esposito MF, McRoberts WP, et al. A systematic literature review of peripheral nerve stimulation therapies for the treatment of pain. Pain Med. 2020 Aug 1;21(8):1590-1603. doi: 10.1093/pm/pnaa030. PMID: 32803220.
4. Deer TR, Lamer TJ, Pope JE, et al. The Neurostimulation Appropriateness Consensus Committee (NACC) safety guidelines for the reduction of severe neurological injury. Neuromodulation. 2017 Jan;20(1):15-30. doi: 10.1111/ner.12564. PMID: 28042918.
5. Deer T, Pope J, Benyamin R, et al. Prospective, multicenter, randomized, double-blinded, partial crossover study to assess the safety and efficacy of the novel neuromodulation system in the treatment of patients with chronic pain of peripheral nerve origin. Neuromodulation. 2016 Jan;19(1):91-100. doi: 10.1111/ner.12381. PMID: 26799373.
6. Eldabe SS, Taylor RS, Goossens S, et al. A randomized controlled trial of subcutaneous nerve stimulation for back pain due to failed back surgery syndrome: The SubQStim study. Neuromodulation. 2019 Jul;22(5):519-528. doi: 10.1111/ner.12784. PMID: 29704437; PMCID: PMC6767391.
7. Gilligan C, Volschenk W, Russo M, et al. ReActiv8-B investigators. An implantable restorative-neurostimulator for refractory mechanical chronic low back pain: a randomized sham-controlled clinical trial. Pain. 2021 Oct 1;162(10):2486-2498. doi: 10.1097/j.pain.0000000000002258. PMID: 34534176; PMCID: PMC8442741.
8. Gilligan C, Volschenk W, Russo M, et al. ReActiv8-B Investigators. Long-term outcomes of restorative neurostimulation in patients with refractory chronic low back pain secondary to multifidus dysfunction: Two-year results of the ReActiv8-B pivotal trial. Neuromodulation. 2023 Jan;26(1):87-97. doi: 10.1016/j.neurom.2021.10.011. PMID: 35088722.
9. Gilmore CA, Deer TR, Desai MJ, et al. Durable patient-reported outcomes following 60-day percutaneous peripheral nerve stimulation (PNS) of the medial branch nerves. Interv Pain Med. 2023 Mar 13;2(1):100243. doi: 10.1016/j.inpm.2023.100243. PMID: 39239603; PMCID: PMC11372989.
10. Gilmore CA, Ilfeld BM, Rosenow JM, et al. Percutaneous 60-day peripheral nerve stimulation implant provides sustained relief of chronic pain following amputation: 12-month follow-up of a randomized, double-blind, placebo-controlled trial. Reg Anesth Pain Med. 2019 Nov 17: rapm-2019-100937. doi: 10.1136/rapm-2019-100937. PMID: 31740443.
11. Helm S, Shirsat N, Calodney A, et al. Peripheral nerve stimulation for chronic pain: A systematic review of effectiveness and safety. Pain Ther. 2021 Dec;10(2):985-1002. doi: 10.1007/s40122-021-00306-4. PMID: 34478120; PMCID: PMC8586061.
12. Ishak B, Campos B, Brunn H, et L. Feasibility, safety, and efficacy of subcutaneous peripheral nerve field stimulation for the treatment of refractory low back pain: A two-year single-center study. Neuroscience. 2018 Sep 1; 387:38-47. doi: 10.1016/j.neuroscience.2017.12. 011.. PMID: 29248528.
13. Istek A, Gungor Ugurlucan F, Yasa C, Gokyildiz S, Yalcin O. Randomized trial of long-term effects of percutaneous tibial nerve stimulation on chronic pelvic pain. Arch Gynecol Obstet. 2014 Aug;290(2):291-8. doi: 10.1007/s00404-014-3190-z. PMID: 24619189.
14. National Institute for Health and Care Excellence. Neurostimulation of lumbar muscles for refractory non-specific chronic low back pain. Interventional procedures guidance [IPG739]. Published: September 22, 2022. Accessed November 19, 2024. https://www.nice.org.uk/guidance
15. National Institute for Health and Care Excellence. Peripheral nerve-field stimulation for chronic low back pain. Interventional procedures guidance [IPG451]. Published: 27 March 2013. Accessed November 19, 2024. https://www.nice.org.uk/guidance

16. Strand N, D'Souza RS, Hagedorn JM, et al. Evidence-based clinical guidelines from the American Society of Pain and Neuroscience for the use of implantable peripheral nerve stimulation in the treatment of chronic pain. J Pain Res. 2022 Aug 23; 15:2483-2504. doi: 10.2147/JPR.S362204. PMID: 36039168; PMCID: PMC9419727.
17. United States Food and Drug Administration (FDA). 510(k) Premarket Approval (PMA): Medtronic Peripheral Nerve Stimulation System for Pain Relief (Medtronic X-trel, Mattrix Neurostimulation). Medtronic Vascular. Minneapolis, MN. Product Code GZB and GZF. PMA: K883780 and K934065. Accessed November 20, 2024. https://www.accessdata.fda.gov.
18. United States Food and Drug Administration (FDA). 510(k) Premarket Approval (PMA): Moventis PNS System. Micron Medical Corporation. Boca Raton, FL. Product Code GZF and GZB. PMA: K200848.Accessed November 20, 2024. https://www.accessdata.fda.gov.
19. United States Food and Drug Administration (FDA). 510(k) Premarket Approval (PMA): Nalu Neurostimulation System. Nalu Medical Inc. Carlsbad, CA. Product Code GZB and GZF. PMA: K221376. Accessed November 20, 2024. https://www.accessdata.fda.gov
20. United States Food and Drug Administration (FDA). 510(k) Premarket Approval (PMA): Neuspera Neurostimulation System (NNS). Neuspera Medical Inc. San Jose, CA. Product Code GZF. PMA: K202781 Accessed November 20, 2024. https://www.accessdata.fda.gov
21. United States Food and Drug Administration (FDA). 510(k) Premarket Approval (PMA): SPRINT Peripheral Nerve Stimulation (PNS) System. SPR Therapeutics Inc. Cleveland, OH. Product Code NHI. PMA: K211801. Accessed November 20, 2024. https://www.accessdata.fda.gov
22. United States Food and Drug Administration (FDA). 510(k) Premarket Approval (PMA): Renew Neurostimulation System. Advanced Neurostimulation Systems. Plano, TX. Product Code GZF and GZB. PMA: K000852. Accessed November 20, 2024. https://www.accessdata.fda.gov
23. United States Food and Drug Administration (FDA). 510(k) Premarket Approval (PMA): StimQ Peripheral Nerve Stimulator (PNS) System. StimQ LLC. Product Code GZF. PMA: K152178. Accessed November 20, 2024. https://www.accessdata.fda.gov
24. United States Food and Drug Administration (FDA). 510(k) Premarket Approval (PMA): StimRouter Neuromodulation System. Bioness Inc. Valencia, CA. Product Code GZF. PMA: K211965. Accessed November 20, 2024. https://www.accessdata.fda.gov
25. Wilson RD, Gunzler DD, Bennett ME, et L. Peripheral nerve stimulation compared with usual care for pain relief of hemiplegic shoulder pain: A randomized controlled trial. Am J Phys Med Rehabil. 2014 Jan;93(1):17-28. doi: 10.1097/PHM.0000000000000011. Erratum in: Am J Phys Med Rehabil. 2016 Feb;95(2): e29. PMID: 24355994; PMCID: PMC4038163.
26. Zelaya CE, Dahlhamer JM, Lucas JW, et al. Chronic pain and high-impact chronic pain among U.S. adults, 2019. NCHS Data Brief No. 390. November 2020. Center for Disease Control and Prevention. CDC.gov. Accessed November 19, 2024.