MEDICAL POLICY

Medical Policy Title	**Implantable and Invasive Neuromodulation Systems**
Policy Number	**1.01.60**
Current Effective Date	**January 1, 2027**
Next Review Date	**May 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

This policy does not address Sacral, Spinal Cord/Dorsal Column Stimulation or Tibial Nerve Stimulation.

POLICY STATEMENT(S)

I. The following implantable and invasive neuromodulation systems are **investigational**:

- A. Peripheral Nerve Stimulation (PNS)- Permanent Systems;
- B. Peripheral Nerve Stimulation (PNS)-Temporary Systems (e.g., SPRINT);
- C. Restorative Neurostimulation (e.g., ReActiv8);
- D. Percutaneous Electrical Nerve Stimulation/Percutaneous Neuromodulation Therapy.

RELATED POLICIES

Corporate Medical Policy

1.01.58 Cranial and Auricular Neuromodulation

01.01 59 Electromagnetic and Pulsed Field Stimulation

1.01.61 Non-Invasive Surface Electrical Stimulation for Pain and Rehabilitation

1.01.62 Specialized Neuromodulation for Specific Conditions

7.01.05 Vagus Nerve Stimulation and Vagus Nerve Blocking Therapy

7.01.10 Sacral Nerve Stimulation

7.01.41 Surgical Management of Sleep Disorders

8.01.22 Tibial Nerve Stimulation (TNS) for Voiding Dysfunction

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Peripheral Nerve Stimulation (PNS)- Permanent Systems

PNS is a similar concept to transcutaneous electrical nerve stimulation (TENS) but different in that electrodes are implanted around or adjacent to the nerve serving the painful stimuli and then stimulated using a pulse generator and remote control. A trial of treatment is typically required prior to permanent implant of the generator and/or electrodes. Success of the trial is defined as >50% reduction in pain response. PNS is generally reserved for patients who fail to get pain relief from TENS, medications, physical therapy or injection therapy.

The Moventis PNS (Micron Medical Corporation) received U.S. Food and Drug Administration (FDA) approval based upon substantial equivalence to The Freedom Spinal Cord Stimulator (SCS) System (Curonix) and an implanted peripheral nerve stimulator (StimQ PNS, Stimwave Technologies) for pain management. All of the devices are intended to treat adults who have severe intractable chronic pain of peripheral origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach and are not intended to treat pain in the craniofacial region of the body.

The Nalu neurostimulation (Nalu Medical, Inc.) system involves a 3-step process: wear experience, therapy trial, and permanent implantation. The treatment involves the initial use of adhesive clips and nonfunctioning Therapy Discs to determine future stimulation location and comfort level, followed by a temporary trial of the implanted leads, prior to permanent implantation. It is used for the management of chronic pain.

Peripheral Nerve Stimulation- Temporary Systems

The SPRINT peripheral nerve stimulation system (SPR Therapeutics, Inc.) is considered a temporary device, SPRINT uses a percutaneous electrode placed via an introducer needle near target peripheral motor or sensory nerves. The insertion of the implant does not require incisions or anesthesia, and the indwelling leads are left in place for up to 60 days. The device utilizes 300-micron diameter leads (one quarter the size of conventional neurostimulation leads) to provide safe lead withdrawal at the completion of the treatment. The device is intended to provide symptomatic relief of chronic, intractable pain, post-surgical and post-traumatic acute pain. It is not intended to treat pain in the craniofacial region of the body.

Restorative Neurostimulation Therapy

The ReActiv8 (Mainstay Medical) device is a permanent implant indicated for adults with intractable chronic low back pain associated with multifidus dysfunction who have failed pain medications and physical therapy and are not candidates for spine surgery. The device components consist of an implantable pulse generator, stimulation leads, software and programmer wand, activator, and magnet. ReActiv8 is marketed as the first and only restorative neurostimulation therapy to treat mechanical chronic low back pain and is full body MRI conditional.

Percutaneous Electrical Nerve Stimulation (PENS)/Percutaneous Neuromodulation Therapy (PNT)

PENS and PNT are terms often used interchangeably in the literature. This form of stimulation utilizes very fine needle-like electrode arrays placed near the painful area to stimulate peripheral sensory nerves in the soft tissue. PENS and PNT are also not to be confused with acupuncture using electrical stimulation. In electrical acupuncture, needle electrodes are inserted below the skin, but not

necessarily at the site of pain. They are placed according to acupuncture meridians, which are a concept of Chinese medicine.

SUPPORTIVE LITERATURE

Peripheral Nerve Stimulation- Permanent Systems

Lin et al (2024) conducted a systematic review and meta-analysis of randomized controlled trials. The authors investigated the effectiveness of peripheral nerve stimulation (PNS) has on pain and improvement in function on post operative lower-limb orthopedic patients. Data was used from eight randomized controlled trials involving 633 patients. While PNS did not significantly reduce pain intensity or improve functional outcomes such as range of motion and length of hospitalization, it did lead to a marginally significant reduction in analgesic consumption. These findings suggest that although PNS may offer some benefit in reducing the need for pain medication, its overall clinical efficacy remains uncertain. The authors recommend future research with larger sample sizes, longer follow-up periods, and varied stimulation parameters to better assess its potential.

Peripheral Nerve Stimulation- Temporary Systems

Gilmore et al (2021) performed a prospective multi-center study aimed at characterizing the responses of percutaneous medial branch peripheral nerve stimulation (PNS) to see if results from earlier, smaller single-center studies and reports were generalizable when performed on a larger number of patients refractory to nonsurgical treatments. Participants (n=89) with chronic lower axial backpain, a pain score greater than or equal to four, had failed at least two different categories of treatments and had at least four weeks of stable analgesic medication usage were enrolled, eight of which were later to be found ineligible because they did not meet the predefined criteria at the baseline. Authors report enrollment stopped short due to COVID-19. Exclusions included history of lumbar surgery, however, 10 of the patients with a history of lumbar surgery were included as part of a prospectively designed sub study with revised exclusion criteria. Participants were implanted with percutaneous PNS leads from the SPRINT PNS System under ultrasound and/or fluoroscopic guidance and were left in place for up to 60-days, when leads were removed. Follow up was planned for 12 months after the two-month PNS treatment. The study was not completed, and follow-up beyond 8 months is on-going. Clinically and statistically significant reductions in pain intensity, disability, and pain interference were reported by a majority of participants. 73% of participants were successful for the primary end point, reporting clinically significant (≥30%) reductions in back pain intensity after the 2-month percutaneous PNS treatment (n = 54/74). Whereas prospective follow-up is ongoing, among those who had already completed the long-term follow-up visits (n = 51), reductions in pain intensity, disability, and pain interference were sustained in a majority of participants through 14 months after the start of treatment. Limitations of the study include lack of randomization and control group.

Restorative Neurostimulation Therapy

ReActiv8 system FDA approval was based on a 2020 randomized control trial by Gilligan and colleagues (ReActiv8-B, NCT02577354). The authors have since published two-year and three-year durability studies on the same participants (Gilligan et al 2021, 2023). The pivotal trial was a multicenter sham controlled RCT enrolling 204 individuals with chronic, refractory low back pain. All

participants were permanently implanted with the system. Therapeutic group participants (n=102) received active treatment of the medial branch of the dorsal ramus nerve for 30-minutes twice daily. The control group (n=102) received low level sham stimulation. The primary endpoint was the difference in proportions of responders in the treatment and control groups. Response was defined as having a 30% or greater reduction in visual analog scale (VAS) and no increase in pain medications, assessed at 120 days. Following the 120-day randomized phase, participants in the control group were given the option to cross over to the intervention group and were followed along with the participants from the intervention group for up to three years. At 120 days, there was no difference between groups on the primary endpoint of treatment response (57.1% intervention vs 46.6% sham; p =.1377) or the individual components of the primary endpoint.

The study investigators conducted prespecified secondary analyses of the primary outcome data, including the between-group difference in VAS at 120 days, a review of participants with increased pain medications, and a cumulative-proportion-of-responders analysis, which graphically displays the proportion of responders across the range of all possible cutoffs and is described as having greater statistical power than the comparison of proportions of the dichotomized primary outcome. The VAS mean change from baseline to 120 days favored the intervention group (-3.3 vs -2.4; p =.032), but it is unclear if the difference between groups (0.9 points) was clinically meaningful. The cumulative proportion-of-responders analysis similarly favored the intervention group (p =.0499). Nine participants in both the intervention and control groups had an increase in pain medication at 120 days, but the increase was unrelated to low back pain in 6 of 9 participants in the treatment group versus 0 of 9 in the control group. Most importantly, the controlled phase was only 120 days. In the longer-term, uncontrolled follow-up phase of the trial, there was continued improvement in VAS scores over time in those who were assessed. Data was available for 176 of 204 participants at 1 year (86.3%), 156 of 204 participants (79%) at two years, and 130 of 204 (63.7%) at three years. The limitations of the studies, including a lack of a control group and high attrition limits drawing conclusions from these results. Additional evidence from longer-term sham controlled RCTs is needed.

Percutaneous Electrical Nerve Stimulation (PENS)/Percutaneous Neuromodulation Therapy (PNT)

PENS has been investigated for the treatment of headache, diabetic neuropathy, chronic neck pain, chronic low back pain, chronic surface hyperalgesia, and musculoskeletal pain. A systematic review conducted by Plaza-Manzano and colleagues (2020) concluded that PENS could decrease the level of pain intensity, but not related disability, in musculoskeletal pain disorders. The overall level of evidence, however, was low and there was heterogeneity in the application methods.

Beltran-Alacreu et al (2022) evaluated the effectiveness of PENS compared to TENS on the reduction of musculoskeletal pain. This systematic review and meta-analysis included a total of nine RCTs in the qualitative analysis, with seven in the quantitative analysis. Overall, there was low-quality evidence for increased pain intensity reduction with PENS over TENS, but the difference found was not deemed to be clinically significant. When only studies with low risk of bias were meta-analyzed, there was a moderate quality of evidence that there is no difference between TENS and PENS for pain intensity. Six out of the nine studies presented high risk for the blinding of participants, and seven out of nine were high risk for blinding of personnel. Beyond these two items, the risk of bias in

the included trials was either low or unclear. Protocols and parameters for the application of PENS and TENS were heterogenous across all trials, leading to the conclusion that there is still high uncertainty regarding the effectiveness of PENS for musculoskeletal pain.

There are no well-designed randomized controlled studies in the medical literature comparing PNS to established treatment options or a sham procedure; and studies on larger populations with longer follow-up are needed to permit scientific conclusions regarding the benefit and improved health outcomes for the use of PNS.

PROFESSIONAL GUIDELINE(S)

The American Society of Pain and Neuroscience 2022 Clinical Guidelines for the Use of Implantable Peripheral Nerve Stimulation in the Treatment of Chronic Pain stated:

Facial Pain

- "Stimulation of occipital nerves may be offered to patients with chronic migraine headache when conservative treatments have failed. The average effect size for relief of migraine symptoms is modest to moderate." (Level I, Grade B)
- "There is insufficient evidence to recommend stimulation of supraorbital and infraorbital nerves for neuropathic craniofacial pain." (Level II-3, Grade C)

Upper Extremities

- "PNS may offer modest and short-term pain relief, improved physical function, and better quality of life for chronic hemiplegic shoulder pain." (Level I, 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." (Level II-2, Grade B)

Lower Back and Trunk

- "Subcutaneous peripheral field stimulation combined with optimal medication management may offer moderate improvement in pain intensity for failed back surgery syndrome compared to optimal medication management alone." (Level I, Grade B)
- "There is evidence that PNS of medial branch nerves may improve pain intensity, physical function, and pain interference in patients with axial, mechanical low back pain." (Level II-2, Grade B)
- "There is limited evidence that PNS alleviates pain in neuropathic pain syndrome involving the trunk and back, including radiculopathy and post-herpetic neuralgia." (Level 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." (Level 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." (Level I, Grade B) (Strand 2022)

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates electrical stimulation devices as medical devices. All electrical stimulation devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Mar 13]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2026 Mar 13]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
64555 (E/I)	Percutaneous implantation of neurostimulator electrode-electrode array; peripheral nerve (excludes sacral nerve)
64575 (E/)	Open implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64585 (E/I)	Revision or removal of peripheral neurostimulator electrode array
64590 (*E/I)	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 (*E/I when services include the use of systems addressed within this policy.)
64596 (E/I)	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; initial electrode array
64999 (E/I)	Unlisted procedure, nervous system (PNS or PNT using needle[s] or needle electrode[s])

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HCPCS Codes

Code	Description
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)

ICD10 Codes

Code	Description
G89.2-G89.4	Chronic pain (code range)
G62.89	Other specified polyneuropathies
M53.86	Other specified dorsopathies, lumbar region
M53.87	Other specified dorsopathies, lumbosacral region
M54.51	Vertebrogenic low back pain
M62.85	Dysfunction of the multifidus muscles, lumbar region
M79.10	Myalgia, unspecified site

REFERENCES

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

NCD-Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (160.7.1) [accessed 2026 Mar 16]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates	
01/01/27	
Date	**Summary of Changes**
01/01/27	• Original effective date