MEDICAL POLICY

Medical Policy Title	**Spinal Cord Stimulation / Dorsal Column Stimulation**
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Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Chronic Intractable Pain Secondary to Failed Back Surgery Syndrome (FBSS)

I. A spinal cord stimulator (SCS) (non-high-frequency or high-frequency [HF10 SCS]) is considered **medically appropriate** for the treatment of chronic intractable pain secondary to failed back surgery syndrome (FBSS) with intractable neuropathic leg pain (after prior surgery in the same spinal region) as follows:

   A. A short-term trial (i.e., greater than 48 hours) spinal cord stimulation (i.e., non-high-frequency or high-frequency [HF 10 SCS]), when **ALL** of the following criteria are met:

      1. There has been a failure of at least six (6) consecutive months of physician-supervised, conservative medical management (e.g., pharmacotherapy, physical therapy, cognitive therapy, and activity lifestyle modification);

      2. Surgical intervention is not indicated, or the patient does not wish to proceed with spinal surgery; **and**

      3. An attestation by a behavioral health provider (i.e., a face-to-face or virtual assessment, with or without psychological questionnaires) reveals no evidence of an inadequately controlled mental or behavioral health conditions/issues (e.g., substance use disorder, depression, or psychosis) that would impact perception of pain, and/or negatively impact the success of an SCS or contraindicate its placement. (See Policy Guidelines).

   B. Permanent implantation of an SCS (i.e., non-high-frequency or high-frequency [HF 10 SCS]) when **BOTH** of the following are met:

      1. **ALL** criteria for the short-term trial SCS are met;

      2. At least a 50% reduction in pain has been demonstrated during a short-term trial of spinal cord stimulation (SCS).

Complex Regional Pain Syndrome (CRPS)/Reflex Sympathetic Dystrophy (RSD)

II. Use of a non-high-frequency dorsal column SCS is considered **medically appropriate** for the treatment of chronic, intractable pain secondary to complex regional pain syndrome (CRPS)/reflex sympathetic dystrophy (RSD) **only** of the upper and lower extremities, as follows:

   A. A short-term trial (i.e., greater than 48 hours) of a non-high-frequency dorsal column SCS, when **ALL** the following criteria are met:

1. Limited to only the extremities and not to the head/face/neck, trunk, perineum/pelvis, or abdominal viscera;
2. Diagnosis of CRPS/RSD as evidenced by **all** the following:
    a. Patient has continuing pain which is disproportionate to any inciting event;
    b. Patient reports **at least one (1)** of the symptoms in **three (3) of the four (4)** following categories:
        i. Sensory: reports of hyperesthesia;
        ii. Vasomotor: reports of temperature asymmetry, skin color changes, or skin color asymmetry;
        iii. Sudomotor/edema: reports of edema, sweating changes, or sweating asymmetry; **or**
        iv. Motor/trophic: reports of decreased range of motion, motor dysfunction (weakness, tremor, dystonia), trophic changes (hair, nail, skin);
    c. On physical examination, patient must display **at least ONE (1)** of the signs in **TWO (2) or more** of the following categories:
        i. Sensory: evidence of hyperalgesia (to pinprick) or allodynia (to light touch),
        ii. Vasomotor: evidence of temperature asymmetry, skin color changes, or asymmetry,
        iii. Sudomotor/edema: evidence of edema, sweating changes, or sweating asymmetry, **or**
        iv. Motor/trophic: evidence of decreased range of motion, motor dysfunction (weakness, tremor, dystonia) or trophic changes (hair, nail, skin); **and**
    d. There is/are no other medical or psychological diagnoses that are concordant with the presenting symptoms, signs, or results of relevant studies (e.g., imaging, electrodiagnostic testing, laboratory testing, etc.).
3. Patient has failed at least six (6) consecutive months of physician-supervised conservative medical management (e.g., pharmacotherapy, physical therapy, cognitive behavioral therapy, or activity lifestyle modification);
4. Surgical intervention is not indicated;
5. An attestation by a behavioral health provider (i.e., a face-to-face or virtual assessment [with or without psychological questionnaires or psychological testing]) reveals no evidence of an inadequately controlled behavioral health condition/issue (e.g., substance use disorder, depression, or psychosis) that would impact perception of pain or negatively impact the success of a SCS or contraindicate its placement.

B. Permanent implantation of a non-high-frequency dorsal column SCS, when **BOTH** of the following are met:

1. ALL criteria for the short-term trial SCS are met;
2. At least a 50% reduction in pain has been demonstrated during a short-term trial of spinal cord stimulation.

Chronic Critical Limb Ischemia (CLI)

III. Use of a non-high-frequency dorsal column SCS is considered medically **appropriate** for treatment of patients with chronic, intractable pain secondary to chronic critical limb ischemia (CLI), as follows:

A. A short-term trial (i.e., greater than 48 hours) of a non-high-frequency dorsal column SCS, when **ALL** the following criteria are met:

1. Attestation from a vascular surgeon that the individual is not a suitable candidate for vascular reconstruction;
2. Patient has a diagnosis of CLI when **all** of the following criteria are met:
   a. Ischemic limb rest pain;
   b. Rutherford Classification Grade II, Category 4 (see Description section), ischemic rest pain that is characterized by **both** of the following:
      i. resting ankle pressure less than 40 mmHg, flat or barely pulsatile ankle or metatarsal pulse volume recording; **and**
      ii. toe pressure less than 30 mmHg;
3. Advanced imaging (i.e., angiographic or computed tomography [CT]/magnetic resonance [MR] imaging) demonstrates multi-level disease with absence of named vessel with flow into the foot; **and**
4. An attestation by a behavioral health provider (i.e., a face-to-face or virtual assessment, with or without psychological questionnaires) reveals no evidence of an inadequately controlled behavioral health conditions/issues (e.g., substance use disorder(s), depression, or psychosis) that would impact perception of pain and/or negatively impact the success of an SCS or contraindicate its placement.

B. Permanent implantation of a non-high-frequency dorsal column SCS, when BOTH of the following are met:

1. ALL criteria for the short-term trial SCS are met;
2. At least a 50% reduction in pain has been demonstrated during a short-term trial of SCS.

Chronic Stable Angina Pectoris/Myocardial Ischemia

IV. Use of a non-high-frequency dorsal column SCS is considered **medically appropriate** for treatment of patients with chronic, intractable pain secondary to chronic stable angina pectoris/myocardial ischemia, as follows:

A. A short-term trial (i.e., greater than 48 hours) of a non-high-frequency dorsal column SCS, when **ALL** the following criteria are met:

1. Angina pectoris is Canadian Cardiovascular Society (CCS) functional class III or class IV (see Description section);
2. An attestation from the patient's treating cardiologist confirms that the individual has **BOTH** of the following:
    a. coronary artery disease (CAD) diagnosis; **and**
    b. the patient is not a suitable candidate for a revascularization procedure;
3. Optimal medical treatment (OMT) that has failed to adequately improve anginal symptoms, including **all** the following:
    a. anti-platelet therapy;
    b. statin and/or other lipid-lowering therapy;
    c. anti-anginal therapy implemented to pursue a goal heart rate of 60 beats per minute; **and**
    d. anti-hypertensive therapy as may be indicated to pursue a goal systolic blood pressure (SBP) of less than 140 mmHG and a goal diastolic blood pressure (DBP) of less than 90 mmHG; **and**
4. An attestation by a behavioral health provider (i.e., a face-to-face or virtual assessment, with or without psychological questionnaires) reveals no evidence of an inadequately controlled behavioral health condition/issue (e.g., substance use disorder(s), depression, or psychosis) that would impact perception of pain and/or negatively impact the success of an SCS or contraindicate its placement.

B. Permanent implantation of a non-high-frequency dorsal column SCS, when **BOTH** of the following are met:

1. ALL criteria for the short-term trial SCS are met;
2. There has been a beneficial clinical response during a short-term trial of SCS.

Replacement

V. Replacement of an existing dorsal column SCS (high-frequency or non-high-frequency) or dorsal root ganglion (DRG) stimulator with another DRG is considered **medically appropriate** when **EITHER** of the following criteria are met:

A. The existing stimulator or battery/generator is malfunctioning, cannot be repaired, and is no longer under warranty; **or**

B. Revision of the electrode percutaneous array(s) or electrode plate/paddle(s) is required.

VI. Replacement of a functioning non-high-frequency dorsal column SCS with a high-frequency SCS is considered **not medically necessary**.

Non-Indications

VII. A repeat trial of spinal cord or dorsal column stimulator (SCS) following the failure of an initial short-term trial is considered **not medically necessary** for any indication.

VIII. A high-frequency or non-high-frequency dorsal column SCS is considered **investigational** for **ANY** other indication, including but not limited to:

A. Post-amputation pain (phantom limb pain);

B. Post-herpetic neuralgia;

C. Peripheral neuropathy (e.g., chronic intractable pain from diabetic sensory neuropathy);

D. Dysesthesias involving the lower extremities secondary to spinal cord injury;

E. Abdominal/pelvic visceral pain;

F. Chronic cervical or lumbar radiculopathy without prior surgery;

G. Chronic cervical, thoracic, or lumbar axial pain without prior spinal surgery;

H. Failed cervical and/or thoracic spinal surgery with intractable neuropathic pain in arms(s) or trunk;

I. Abdominal pain related to celiac artery compression syndrome;

J. Neuropathic pain associated with Multiple Sclerosis.

IX. A high-frequency SCS is considered **investigational** for **ALL** other indications, including CRPS/RSD.

X. Dorsal root ganglion (DRG) stimulation, including replacement of a dorsal column SCS with a DRG stimulator, is considered **investigational** for **ALL** indications, except as noted in Policy Statement V.

XI. Generator modes other than tonic-low and high-frequency (e.g., burst stimulation) are considered **investigational**.

XII. Peripheral nerve stimulation, including peripheral nerve field stimulation is considered **investigational** for treatment of acute or chronic pain conditions, including **ANY** of the following;

A. FBSS with intractable neuropathic leg pain;

B. CRPS/RSD;

C. CLI;

D. Chronic, stable angina pectoris;

E. Post-amputation pain (phantom limb pain);

F. Post-herpetic neuralgia;

G. Peripheral neuropathy;

H. Dysesthesias involving the lower extremities secondary to spinal cord injury

RELATED POLICIES

Corporate Medical Policy

1.01.55 Electrical Stimulation as a Treatment for Pain and Other Medical Conditions, for peripheral nerve stimulation (PNS)

3.01.02 Psychological Testing

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. This medical policy does not apply to simple or complex brain, occipital nerve, or peripheral (i.e., cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter.

II. A dorsal column SCS capable of using either high-frequency or non-high-frequency stimulation (dual-mode) is considered an equally effective alternative (when the device uses non-high-frequency stimulation) for the treatment of any of the medically necessary indications listed above.

III. A dorsal column stimulator using high-frequency is considered an equally effective alternative to non-high-frequency stimulation only for the treatment of chronic, intractable pain secondary to failed back surgery syndrome (FBS).

IV. The implantation of an SCS is used only as a last resort. Other treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) need to have been tried and failed or have been judged unsuitable or contraindicated.

V. Patients must be carefully screened, evaluated, and diagnosed by a multidisciplinary team, prior to application of these therapies. This evaluation may include a psychological evaluation/assessment to exclude any psychiatric or psychosocial history that would negatively influence the outcome of the treatment. Psychological testing is not specifically required; however, if necessary, please to refer to Corporate Medical Policy #3.01.02 Psychological Testing.

DESCRIPTION

Spinal cord stimulation is a technique for the treatment of chronic pain and involves implantation of electrodes in the epidural space to provide electrical impulses to the spinal cord to inhibit pain transmission to the brain. The procedure initially involves a short-term trial (e. g., greater than 48 hours) of percutaneous temporary spinal cord stimulation to determine whether the spinal cord stimulator device will induce sufficient pain relief to render permanent implantation medically necessary.

Definitions

Complex Regional Pain Syndrome (CRPS) (as defined by the International Association for the Study of Pain [IASP]) is variety of painful conditions following injury which appear regionally having a distal predominance of abnormal findings, exceeding in both magnitude and duration the expected clinical course of the inciting event and often resulting in significant impairment of motor function, and showing variable progression over time. In addition to injury, CRPS can a so occur as a result of various medical disorders or illnesses.

Critical Limb Ischemia (CLI) is a clinical syndrome of ischemic pain at rest and ischemic tissue loss such as non-healing ulcers or gangrene, related to peripheral artery disease (PAD) of the lower limbs. Spinal stimulators may be appropriate for the treatment of intractable rest pain secondary to chronic limb ischemia.

- Ischemic Rest Pain is pain that occurs in the toes or in the area of the metatarsal heads. Occasionally, it occurs in the foot proximal to the metatarsal heads. Elevation of the limb above or at the horizontal position aggravates the pain and pendency, to some degree at least, brings relief. The pain is secondary to severe arterial insufficiency resulting in inadequate perfusion to the distal lower extremity.
- Refer to Rutherford classification table below.

Dorsal Root Ganglion (DRG) Stimulation is an emerging method of treatment for neuropathic pain. With DRG stimulation, leads are placed percutaneously into the epidural space under fluoroscopic guidance directly over the targeted dorsal root ganglion within the lumbar or sacral region of the spine. The procedure initially involves a short-term trial (i.e., greater than 48 hours) using an external pulse generator; upon success of the initial a permanent pulse generator may then be implanted.

- At this time, the evidence in the peer-reviewed scientific literature is insufficient to support long-term safety and efficacy. The use of this technology for treatment of pain conditions rem ins under investigation.

Failed Back Surgery Syndrome (FBSS) is lumbar spinal pain of unknown origin despite surgical intervention or appearing after surgical intervention for spinal pain originally in the same spinal region. Procedures/surgery that do not encroach into the spinal canal (e.g., interspinous/interlaminar/facet distraction, kyphoplasty/vertebroplasty surgery, etc.) are not considered surgical interventions associated with FBSS.

High-Frequency Spinal Cord Stimulation (HF-SCS), (also referred to as kilohertz frequency spinal cord stimulation or HF10) is a type of spinal cord stimulation (SCS) providing a higher frequency than traditional spinal cord stimulator systems. The HF10 SCS uses low-amplitude, high-frequency, and short-duration pulses. HF10 SCS does not generate paresthesia and operates at a frequency of 10,000 Hz to provide pain relief in comparison to traditional spinal cord stimulation systems, which operate at a frequency in the range of 40-60 Hz and do generate paresthesia. As an alternative to traditional dorsal spinal column stimulation, HF10 SCS is proven safe and effective for treatment of chronic, intractable low back and leg pain in patients with failed back surgery syndrome (FBSS).

Peripheral Nerve Field Stimulation is a technology that involves placement of electrodes subcutaneously within an area of maximal pain, with the objective of stimulating a region of affected

nerves to reduce pain. Depending on the targeted nerve, leads may be placed percutaneously just under the skin or via an open approach for larger deeper peripheral nerves. The use of this technology (used alone or in combination with spinal cord stimulation) for treatment of pain conditions is under investigation.

Peripheral Nerve Stimulation involves implantation of electrodes near or on a peripheral nerve to reduce pain. The use of this technology (used alone or in combination with spinal cord stimulation) for treatment of pain conditions is under investigation.

Spinal Cord Stimulation (SCS), (also known as dorsal column stimulation or neuromodulation) is a reversible therapy applied for neuropathic pain with techniques that include multi-output implanted pulse generator and a choice of electrodes, some of which can be placed percutaneously. The technical goal of this therapy is to achieve stimulation of paresthesia of the dorsal horn of the spinal cord at a subjectively comfortable level, overlapping an individual's topography of pain.

Rutherford Classification (Rutherford 1997). Refer to the policy statement for treatment of patients with chronic, intractable pain secondary to chronic critical limb ischemia (CLI):

Grade	Category	Clinical Description	Objective Criteria
0	0	Asymptomatic- no hemodynamically significant occlusive disease	Normal treadmill or reactive hyperemia test
	1	Mild claudication	Completes treadmill exercise; AP after exercise > 50 mmHg, but at least 20 mmHg lower than resting value
I	2	Moderate claudication	Between categories 1 and 3
	3	Severe claudication	Cannot complete standard treadmill exercise and AP after exercise < 50 mmHg
II	4	Ischemic rest pain	Resting AP < 40 mmHg, flat or barely pulsatile ankle or metatarsal PVR; TP < 30 mmHg
III	5	Minor tissue loss non-healing ulcer, focal gangrene with diffuse pedal ischemia	Resting AP < 60 mmHg, ankle or metatarsal PVR flat or barely pulsatile; TP < 40 mmHg
	6	Major tissue loss- extending above TM level, functional foot no longer salvageable	Same as category 5

AP: ankle pressure; PVR: pulse volume recording; TM: trans metatarsal; TP: toe pressure

Classifications of Cardiovascular Disability (refer to the policy statement for treatment of patients with chronic, intractable pain secondary to chronic stable angina pectoris or myocardial ischemia).		
Class	**New York Heart Association Functional Classification**	**Canadian Cardiovascular Society (CCS) Functional Classifications.**
I	Patients with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.	Ordinary physical activity does not cause angina, such as walking and climbing stairs. Angina occurs with strenuous, rapid, or prolonged exertion at work or recreation.
II	Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.	Slight limitation of ordinary activity. Walking or climbing stairs rapidly, walking uphill, walking or stair-climbing after meals, in cold, in wind, or under emotional stress, or only during the few hours after awakening. Walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions.
III	Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain.	Marked limitation of ordinary physical activity. Walking one to two blocks on the level and climbing one flight in normal conditions and at a normal pace.
IV	Patient with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.	Inability to carry on any physical activity without discomfort—anginal syndrome may be present at rest.
(Heart Failure Society of America [HFSA], 2006; Gibbons, 2002; American Heart Association [AHA], 1994; Canadian Cardiovascular Society [CCS], 1976).		

SUPPORTIVE LITERATURE

Traditional Spinal Cord Stimulation

There is sufficient evidence in the peer-reviewed literature to permit conclusions that the technology provides significant and sustained relief of pain with minimal side effects in appropriately selected patients with chronic, nonmalignant pain. Studies investigating the effectiveness of spinal cord stimulation as a treatment for patients with chronic back/extremity pain report successful management of pain, a substantial decrease in narcotic use, and an improvement in the quality of life. Studies support the use of spinal cord stimulation for patients with CRPS in the upper extremities through outcomes that demonstrate reduction in pain intensity and increased quality of life (e.g., Harke 2005; Kemler 2006; Kumar 2011; Geurts 2013).

One essential step toward the effective use of SCS devices in potential patients is a trial of the system through percutaneous lead placement. This trial will determine the effectiveness in relieving pain (greater than 50% pain relief) and improving the quality of life in patients with refractory neuropathic pain.

Literature exists to support the value of a presurgical psychological evaluation, to identify factors that may adversely impact functional outcomes after spinal cord stimulation (Doleys, 2006; Heckler 2007; Celestin 2009; NASS, 2017).

There is evidence to favor SCS over standard conservative treatment to improve limb salvage and clinical situations in patients with inoperable CLI (Ubbink 2013; Conte 2019; Asimakidou 2022; Piedade 2023).

Studies found that SCS improved both the quality of life and cardiac parameters of patients with refractory angina pectoris (Pan 2017).

SCS has also been investigated as a treatment for pain associated with cervical trauma or disc herniation, however further research is needed on the use of SCS treat patients with cervical trauma/disc herniation presenting with arm pain, neck pain, and/or cervicogenic headache.

In 2023, authors of a large (n=7560) real-world, propensity-matched, comparative effectiveness research study reported findings and conclusion that permanent SCS placement was not associated with a meaningful reduction in use of pharmacologic (including opioids) or nonpharmacologic interventions used for chronic pain at 2 years (Dhruva 2023). Although the authors noted six limitations of their study (e.g., observational study design, inability to distinguish the benefit from SCS but required mediations/procedures for other areas of pain, functional measures such as quality of life were not assessed), the authors concluded the results suggest a lack of clinical benefit for most patients and possible harm to some, and suggest that there may be opportunities to redeploy the high—and increasing—use and spending associated with SCS toward more evidence-based interventions for chronic pain relief.

High-Frequency Stimulation for Refractory Chronic Trunk or Limb Pain

As an alternative to traditional dorsal spinal column stimulation, HF 10 spinal cord stimulation is proven safe and effective for the treatment of chronic, intractable low-back and leg pain in patients

with FBSS (Perruchoud 2013; Kapural 2015 and 2016; Bicket 2016; De Andres 2017; Bolash 2019; Petersen 2021; Kapural 2022).

Spinal Cord Stimulation for Painful Diabetic Neuropathy (PDN)

The SENZA-PDN randomized controlled trial aimed to document the value of 10-kHz SCS in addition to conventional medical management (CMM) compared with CMM alone in patients with refractory PDN (Mekhail 2020). Participants with painful diabetic neuropathy (baseline lower limb Visual Analogue Scale [VAS] ≥5) refractory to prior pharmacological treatment were randomized to high-frequency spinal cord stimulation plus CMM (n=113) versus CMM alone (n=103). All participants randomized to high-frequency spinal cord stimulation underwent a trial stimulation period and participants were eligible for permanent implantation of the stimulation device if at least 50% pain relief was achieved during the trial period. Participants remained in their randomized groups for 6 months, after which time they were eligible to crossover to the other group in the event of inadequate pain relief. The addition of high-frequency spinal cord stimulation to conventional medical management was associated with significantly improved pain scores at 6-month follow-up.

Petersen and colleagues (2021, 2022, 2023, 2025) reported long-term follow-up results from the SENZA-PDN randomized controlled trial (RTC). At 6-month follow-up, 187 patients were evaluated. The primary end point assessed in the intention-to-treat population was met by 5 of 94 patients in the CMM group (5%) and 75 of 95 patients in the 10-kHz SCS plus CMM group ($p < .001$). Infections requiring device explant occurred in 2 patients in the 10-kHz SCS plus CMM group (2%). For the CMM group, the mean pain VAS score was 7.0 cm at baseline and 6.9 cm at 6 months. For the 10-kHz SCS plus CMM group, the mean pain VAS score was 7.6 cm at baseline and 1.7 cm at 6 months. Investigators observed neurological examination improvements for 3 of 92 patients in the CMM group (3%) and 52 of 84 in the 10-kHz SCS plus CMM group (62%) at 6 months ($p < .001$). Substantial pain relief and improved health-related quality of life sustained over 6 months demonstrates 10-kHz SCS can safely and effectively treat patients with refractory PDN. The 12-month follow-up results were consistent in finding a significant pain benefit for high-frequency SCS plus CMM versus CMM alone (Petersen 2022). Investigators reported neurological improvements, particularly improved sensory function, maintained over 12 months for the majority of patients with 10-kHz SCS: 68% (52 of 76) of participants originally assigned to SCS and 62% (32 of 52) of participants after crossover. Findings for the crossover group replicated the findings from the original implant group, providing a cumulative sample of 154 implanted patients with long-term data. Five (3.2%) SCS systems were explanted due to infection. At 24-months, a total of 142 patients completed follow-up. After 24 months of 10 kHz SCS, the mean lower limb pain VAS score in the group of all implanted patients decreased from a preimplantation mean of 7.6 cm to 1.5 cm ($p<.001$). Pain relief and percentage pain relief at 24 months were consistent between the original 10 kHz SCS+CMM group and the CMM-to-10 kHz SCS+CMM crossover cohort ($P =.22$ for pain relief and $p=.12$ for percentage of pain relief). At 24 months, 90.1% of the implanted patients were responders, with 65.5% classified as profound responders, and no patients had increased pain relative to baseline (Petersen 2023). After 24 months of 10 kHz SCS, 92 of 140 implanted individuals exhibited a clinically meaningful improvement over study baseline in sensory, motor, or reflex function, without worsening in any category. Most of the neurological gains were observed in sensory function. Additionally, the reported neurological and sensory improvement outcomes were similar between the original 10 kHz SCS+CMM group and the

CMM-to-10 kHz SCS+CMM crossover cohort, with the initial 10 kHz SCS recipients showing higher improvement rates that reached statistical significance for neurological function at 24 months post-implantation (P =.048 for neurological improvement and P =.076 for sensory improvement).

In 2025, two years after the end of the SENZA-PDN, results of a post-study survey was published (Peterson 2025). A total of 57 former study participants completed the post-survey study, with a median time of 4.1 years since implantation. Among the surveyed participants, 76.8% (43 of 56) reported clinically meaningful pain relief (≥2 points), and 84.6% (44 of 52) achieved a clinically meaningful improvement in their EQ-5D-5L index score. Additionally, 74.5% (38 of 51) reported being "better" or "a great deal better" on the Patient Global Impression of Change (PGIC) scale. The surveyed participants reported a mean HbA1c level decrease of 0.4% ($p = 0.027$), with a more substantial improvement of 1.6% ($p < 0.001$) among those with type 2 diabetes (T2D) and a higher preimplantation HbA1c (>8%). Significant weight loss was also observed, with a mean reduction of 7.0 kilograms (kg) ($p < 0.001$) in the overall cohort and 8.7 kg ($p < 0.001$) in the subgroup with T2D and a higher BMI at preimplantation. There were no explants due to inefficacy during the follow-up period. Study limitations include the use of different pain scales during the SENZA-PDN study and longer-term follow-up, patient reported weight measurements, and results are from a subset of the original study population because not all participants responded. The authors concluded that this longer-term post-study survey, at a mean duration of 4.1 years post-implantation, demonstrates the long-term durability of 10 kHz SCS in managing PDN.

Zuidema and colleagues (2022) reported long-term (8 to 10 years) follow-up of a cohort of patients with painful diabetic neuropathy (PDN) in the lower limbs, evaluating patients who still used SCS device ≥ eight years after implantation. This study is a follow-up of the remaining patients from the pilot study (Pluijms 2012) and RCTs (Slangen 2014; van Beek 2015 and 2018). Pain intensity, day and night, was significantly ($p < 0.01$) reduced by 2.3 (NRS 6.6–4.3) and 2.2 (NRS 6.8–4.6) points, respectively, when comparing the long-term data with baseline. A total of 19 patients were included in this follow-up, with two patients (10%) diagnosed with diabetes mellitus (DM) type 1 and the remaining 17 patients (90%) having DM type 2. For > 50% of patients, the reduction in pain intensity (day and night) was ≥ 30%, which is considered clinically meaningful. Some of these patients achieved reductions ≥ 50%, indicating high response to treatment. There were no differences in quality-of-life measures between baseline and long-term follow-up, and no differences were found in sleep quality or depressive symptoms. According to the authors, these findings show that SCS is a relatively safe treatment and can remain effective in reducing pain intensity in the long term.

In 2022, a systematic review and network meta-analysis of neurostimulation for PDN was conducted of the published literature until December 2021 (Duarte 2022). Three RCTs were included in the review, with a total of 272 participants. The network meta-analysis showed that low- and high-frequency spinal cord stimulation (SCS) resulted in statistically significant reductions in pain intensity, a higher proportion of patients obtaining at least 50% pain reduction, and improvements in quality-of-life index scores at the 6-month follow-up. There was a significantly greater reduction in pain intensity on high-frequency-SCS (HF-SCS) compared with low-frequency-SCS (LF-SCS) at the 6-month but not 3-month follow-up. Although the RCTs were well designed, the open-label design and pain as a subjective outcome mean that the RCTs are at high risk of bias. Current evidence shows

that both LF-SCS and HF-SCS provide more benefits than conventional medical management for patients with PDN. HF-SCS was found to have the highest probability of being the best treatment option. However, while HF-SCS may reduce pain intensity compared with LF-SCS, no differences were observed for the other outcomes, including overall health-related quality of life. In the absence of head-to-head RCT evidence, the relative benefits of HF-SCS compared with LF-SCS for patients with PDN remain uncertain.

Chen and colleagues (2022) analyzed the effectiveness of high-frequency 10 kHz SCS in patients diagnosed with PDN in a retrospective, real-world, multicenter patient cohort (n=89). Inclusion criteria included patients aged ≥18 years of age with diabetic neuropathy who were trialed and permanently implanted with a 10 kHz SCS device between May 2017 and November 2020. Patients who reported at least 50% pain relief during the trial period were eligible to receive permanent device implantation. Patients were assessed for baseline prior to 10 kHz SCS trial and at regular follow-up visits after device implantation. Responders were defined as those who reported at least 50% pain relief compared to baseline. At the last assessment, 79.5% (58/73) of patients were treatment responders over an average follow-up of 21.8 months (range: 4.3-46.3 months). The average reduction in pain during the assessment period was 60.5%. The authors reported that this real-world study concurs with findings from another RCT, and outcomes demonstrated durability up to a maximum of 46.3 months; however, the results have limitations and should be interpreted with caution.

Spinal Cord Stimulation for Multiple Sclerosis Symptoms

Two systematic reviews were conducted to evaluate the effectiveness of SCS in patients with multiple sclerosis (MS). Rapisarda and colleagues (2021) reviewed seven studies, with 373 MS patients submitted to a stimulation trial and 82 MS patients underwent a de novo implantation. The authors reported long-lasting improvement in 193/346 (55.8%) MS patients with motor disorders, in 90/134 (67.13%) MS patients with urinary dysfunction, and in 28/34 (82.35%) MS patients with neuropathic pain. The efficacy of SCS was higher for urinary dysfunction (p =0.0144) and neuropathic pain (p= 0.0030) compared with motor disorders. Conclusions. According to the authors, this systematic review provides evidence that SCS is effective in MS patients, with symptoms of urinary dysfunction and pain being the most responsive to SCS. Further studies are needed to improve the patient selection and clarify the best timing to perform SCS in these patients.

Goodwin and colleagues (2023) analyzed the data from 16 articles to determine the efficacy of SCS in the treatment of MS spasticity and concluded that “although a unique modality, there is not enough evidence to support the employment of SCS over current medical standard of care.”

Burst Stimulation

Hou and colleagues (2016) published a systematic review of burst spinal cord stimulation for the treatment of chronic back and limb pain. Reviewers identified five studies of burst spinal cord stimulation in patients with intractable chronic pain of more than 3 months in duration who had failed conservative treatment. Three studies, with sample sizes of 12, 15, and 20, respectively, used randomized crossover designs to compare burst stimulation with tonic stimulation; 2 studies also included a placebo stimulation intervention. Also, there were 2 case series with sample sizes of 22

and 48 patients, respectively. Data were collected after 1 to 2 weeks of treatment and study findings were not pooled. Overall, the level of confidence in the evidence on burst spinal cord stimulation for treating chronic pain without paresthesia was rated as "very low."

The SUNBURST (Success Using Neuromodulation with BURST) trial (Deer 2018) was designed to assess the effects of Burst stimulation from St Jude Medical and enrolled 100 patients from 20 centers across the United States randomized to either receive tonic stimulation prior to Burst stimulation, or to receive Burst stimulation prior to tonic stimulation. Forty-five patients were randomized to spinal cord stimulation then burst, and the remaining 55 were randomized to burst then spinal cord stimulation. At the end of the second crossover period, patients were allowed to choose the stimulation mode they preferred and were followed for one year. The study met its primary endpoint of non-inferiority and achieved statistical significance for its pre-specified secondary endpoint of superiority demonstrating patients receiving St. Jude Medical's Burst stimulation achieved superior pain relief and greater treatment success when compared to patients receiving traditional SCS. The estimated difference in the overall visual analog scale score between burst and spinal cord stimulation was -5.1 mm (95% upper CI, -1.14 mm), demonstrating noninferiority ($p<0.001$) and superiority ($p<0.017$). The proportion of patients with a decrease in visual analog scale score of 30% or more was 60% (60/100) during burst stimulation and 51% (51/100) during spinal cord stimulation. The proportion of patients whose global impression was minimally improved, moderately improved, or very much improved was approximately 74% in both groups. The authors reported that the programming parameters were not standardized at the beginning of the study but a more standardized approach with lower amplitudes was implemented as the trial was ongoing. Trial limitations included the crossover design, which limits comparison of pain over longer periods of time, lack of blinding, and variable burst programming parameters.

Dorsal Root Ganglion Stimulation

Deer and colleagues (2017) conducted the ACCURATE study, which compared dorsal root ganglion neurostimulation with standard spinal cord stimulation. Eligibility criteria for this multicenter, unblinded, noninferiority trial included chronic (≥6 months) intractable (failed ≥2 drugs from different classes) neuropathic pain of the lower limbs associated with a diagnosis of CRPS or causalgia and no previous neurostimulation. Patients were randomized to dorsal root ganglion stimulation with the Axium device or standard spinal cord stimulation. Patients first underwent a temporary trial of stimulation lasting 3 to 30 days, depending on the protocol at each site. Patients who had a 50% or greater reduction in lower limb pain after the temporary trial were eligible for permanent stimulation. Those who failed temporary stimulation exited the trial but were included in the analysis as treatment failures. A total of 152 patients were randomized, and 115 (n=61 dorsal root ganglion, n=54 spinal cord stimulation) had a successful temporary trial and continued to permanent implantation. The primary outcome was a composite measure of treatment success. Success was defined as a 50% or greater reduction in VAS score and no stimulation-related neurologic deficits. The noninferiority margin was set at 10%. No patients experienced neurologic deficits in either group. Regarding paresthesias, at 3 months and 12 months, spinal cord stimulation patients were significantly more likely to report paresthesias in nonpainful areas than dorsal root ganglion patients. At 3 months, 84.7% of dorsal root ganglion patients and 65% of spinal cord stimulation patients reported paresthesias only in their painful areas; at 12 months, these percentages were 94.5% and 61.2%,

respectively.

Mekhail and colleagues (2019) conducted a sub-analysis on the patients receiving dorsal root ganglion neurostimulation in the ACCURATE study, to evaluate the occurrence and risk factors for paresthesia. Among the 61 patients with dorsal root ganglion implants, the rates of paresthesia at 1 month, 3 months, 6 months, 9 months, and 12 months were 84%, 84%, 66%, 62%, and 62%, respectively. The patients who were paresthesia-free reported similar or better outcomes for pain and quality of life. Risk factors for paresthesia occurrence included higher stimulation amplitudes and frequencies, number of implanted leads, and younger age. The authors reported that many subjects with lower-extremity chronic pain due to CRPS-I or CRPS-II from the ACCURATE study obtained paresthesia-free pain relief with DRG stimulation, and paresthesia-free subjects had the same or better outcomes as subjects with paresthesia-present DRG stimulation. The authors concluded that these results support the observation that paresthesia may not be required for optimal analgesia with DRG stimulation for all subjects.

Sivanesan and colleagues (2019) performed a retrospective analysis of the FDA's Manufacturer and User Facility Device Experience (MAUDE) database provided information on complications related to the use of DRG stimulation The MAUDE database was queried for dorsal root ganglion stimulation reports through 2017, identifying 979 episodes. Complications were predominantly device-related (47%; lead migration and lead damage), with the remaining comprised of procedural complications (28%; infection, new neurologic symptoms, and dural puncture), patient complaints (12%; site pain and unwanted stimulation), serious adverse events (2.4%), and "other" complications (4.6%). The prevalence of complications cannot be estimated using the MAUDE database; while facilities are mandated to report events, patients and health care providers may report events, but are not mandated to do so.

Several systematic reviews of dorsal root ganglion devices have been published including Vuka (2019) and Deer (2020). Moman and colleagues (2021) report that although DRG stimulation has superior efficacy in complex regional pain syndrome compared to spinal cord stimulation (SCS) and may have efficacy in other forms of chronic pain, there is less available safety information for DRGS. The objectives of the systematic review and pooled analysis of incidence was to determine the overall incidence of DRG stimulation infections, incidence at each stage (trial vs implant vs revision), infection characteristics, and outcomes. Ten studies met inclusion criteria. Eight studies reported patients with trial data (n = 291), ten studies reported patients with implant data (n = 250), and seven studies reported data with revisions (n = 26). The pooled incidence of trial infections was 1.03%, implant infections was 4.80%, revision infections was 3.85%, and overall infections was 2.82%. There was a statistically significant difference in infection rates between the trial, implant, and revision stages (p = 0.01). A DRG stimulation trial appears to be low risk for infection, but that risk is significantly increased with DRG stimulation implant. The findings highlight the need for further study of infectious complications, their risks, and optimal prophylaxis.

D’Souza and colleagues (2022) appraised the current evidence for DRG stimulation in the treatment of lower extremity neuropathic pain. The evidence base for DRG stimulation for the treatment of CRPS type I or CRPS type II included one RCT and 11 observational studies reporting outcomes between 3 and 36 months. There is low-quality evidence highlighting that DRG stimulation is

associated with improved pain intensity in lower extremity CRPS. There is very low-quality evidence highlighting that pain relief may be achieved with DRG stimulation for PDN, focal neuropathy, polyneuropathy, and postsurgical neuropathic pain of the groin and knee. Future high-quality and adequately powered RCTs within more homogeneous participant populations are warranted assessing the utility of DRG stimulation in lower extremity neuropathic pain syndromes.

Peripheral Nerve Field Stimulation (PNFS)

Peripheral nerve field stimulation (also known as peripheral subcutaneous field stimulation) is a form of neuromodulation intended to treat chronic neuropathic pain by placing leads subcutaneously within the area of maximal pain. This technique is different from peripheral nerve stimulation (PNS) whereby specific, visible and identifiable peripheral nerves are target. PNFS is being investigated for low back pain, neck and shoulder pain, inguinal and pelvic pain, thoracic pain, abdominal pain, fibromyalgia, and postherpetic neuralgia.

The evidence is insufficient to determine that the technology results in an improvement in the net health outcome (Verrills 2011 and 2014; Mironer 2011; McRoberts 2013; Kloimstein 2014; Eldabe 2019).

Van Herern and colleagues (2023) conducted a comparative study of patients with persistent spinal pain syndrome (PSPS) who responded to treatment with either SCS + PNFS or SCS only following a multicenter randomized clinical trial protocol. In total, 75 patients completed the 12-month follow-up (21 in the SCS-only group and 54 in the SCS + PNFS group). Outcome measures were pain (visual analog scale), quality of life (36-Item Short Form Survey [SF-36]), anxiety and depression (Hospital Anxiety and Depression Scale [HADS]), overall health (EuroQol Five-Dimension [EQ-5D]), disability (Oswestry Disability Index [ODI]), and pain assessed by the McGill questionnaire. There were no significant differences in baseline characteristics between the two groups. Both groups showed a significant reduction in back and leg pain at 12 months compared with baseline measurements. No significant differences were found between the groups in effect on both primary (pain) and secondary parameters (SF-36, HADS, EQ-5D, ODI, and McGill pain).

Closed-Loop Spinal Cord Stimulation

A novel spinal cord stimulation system, the Evoke Spinal Cord Stimulation (SCS) System, provides the first in vivo, real-time, continuous objective measure of spinal cord activation in response to therapy via recorded evoked compound action potentials (ECAPs) in patients during daily use. The Evoke SCS System is an implanted, rechargeable spinal cord stimulation system intended to treat long-term (chronic) pain in the trunk or limbs that are difficult to manage (intractable). The system is designed to operate in either of two modes: an evoked compound action potential (ECAP) controlled closed-loop stimulation mode or an open-loop (fixed output) stimulation mode. The open-loop stimulation mode is equivalent to that of traditional SCS, and the closed-loop purportedly can provide real-time measurement and automatic adjustment of the strength of the stimulation based on the reading, recording, and response to the ECAP.

Mekhail and colleagues (2020 and 2022) designed a study to examine pain relief and the extent of spinal cord activation with evoked compound action potentials (ECAPs)-controlled closed-loop versus fixed-output, open-loop spinal cord stimulation for the treatment of chronic back and leg pain. This

study is the first to record in-vivo human spinal cord electrophysiology in both stimulation modes and reported that more closed-loop group patients as responders (≥50% reduction) in overall pain 53 of 67 [79.1%] versus 36 of 67 [53.7%] in the open-loop group.

Brooker and colleagues (2021) reported research findings from the Avalon study, which was also designed to investigate the use of the first closed-loop SCS system in patients with chronic pain. This is a prospective, multicenter, single-arm study where 50 patients were enrolled and followed at one, three, six, 12, 15, 18, 21, and 24 months post permanent implantation of the Evoke SCS System. Although the reported 24-month results support the 12-month results of both this Avalon study and the Evoke study, the study has limitations, and the technology remains under investigation.

PROFESSIONAL GUIDELINE(S)

North American Spine Society's (NASS 2017) coverage recommendations outline contradictions to SCS, including repeating an SCS trial in the same region with the same or similar device for a previously failed trial existing and for untreated drug addiction or poorly controlled psychiatric/psychological disorders and pregnancy. Demand-type cardiac pacemakers are considered a relative contraindication, as it is necessary to interrogate the pacemaker device during the trial to ensure that there is no interference between the SCS pulse generator and the pacemaker.

The International Neuromodulation Society convened a Neuromodulation Appropriateness Consensus Committee (NACC) to develop best practices for the use of DRG stimulation for the treatment of chronic pain syndromes (Deer 2019). The NACC performed a systematic literature search through June 2017 and identified 29 publications providing evidence for the consensus recommendations. The expert panel concluded that DRG stimulation for PDN may be effective based on limited data, but since there is good evidence for SCS, the use of DRG must be justified (Grade C, moderate consensus).

Grade A (strong consensus) recommendations include:

- DRG stimulation is superior to standard SCS for unilateral focal pain from CRPS type I or type II of the lower extremity.
- DRG stimulation is recommended for CRPS type I or type II of the lower extremity.
- DRG stimulation for CRPS type I or type II of the upper extremity requires more study.
- DRG stimulation is superior to standard SCS for unilateral focal pain from CRPS type I or type II of the lower extremity.

In 2022, the American Association of Clinical Endocrinology published evidence-based recommendations for the care of individuals with diabetes mellitus (Blonde 2022). The guidelines state that "neuromodulatory techniques such as high-frequency spinal cord stimulation and combining pharmacological with nonpharmacological approaches should be considered in those with refractory painful diabetic peripheral neuropathy. " (Grade B).

The American Society of Pain and Neuroscience (ASPN) published consensus guidelines on interventional therapies for back pain (Sayed 2022). The guidelines recommendations for spinal cord stimulation following lumbar surgery (Grade A), for treatment of non-surgical low back pain (Grade

B), and in the treatment of patients with predominate lumbar spinal stenosis (Grade C).

In 2023, the American Society of Regional Anesthesia and Pain Medicine (ASRAPM) issued evidence-based consensus guidelines on patient selection and trial stimulation for spinal cord stimulation (SCS) for treatment of chronic non-cancer pain (Shanthanna 2023). Following a comprehensive literature review, the guidelines recommend a trial of SCS therapy before performing a definitive SCS implant, with the exception of patients with chronic anginal pain who are not surgical candidates for coronary artery bypass surgery. Improved pain relief of ≥50% must be demonstrated using a validated outcome instrument, during or at the end of trial, to be considered successful. ASRAPM recommends that all patients are appropriately screened, using objective validated instruments, for high-risk psycho-social factors including depression.

Peripheral Nerve Field Stimulation (PNFS)

In 2013, without more recent update, NICE issued guidance on peripheral subcutaneous field stimulation for chronic low back pain, which stated "Current evidence on the efficacy of peripheral nerve-field stimulation for chronic low back pain is limited in both quantity and quality, and duration of follow-up is limited. Evidence on safety is also limited and there is a risk of complications from any implanted device."

REGULATORY STATUS

A large number of neurostimulator devices have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process under FDA product code: LGW (stimulator, spinal-cord, totally implanted for pain relief), PMP (Dorsal Root Ganglion Stimulator for Pain Relief), and GZB (Stimulator, Spinal-Cord, Implanted [Pain Relief]).

In September 2020, the FDA released a letter to healthcare providers reminding them to conduct a trial stimulation period before implanting a spinal cord stimulator as the agency continues to receive reports of serious adverse effects associated with these devices.

Traditional Stimulation

Totally implantable dorsal column SCS systems are regulated by the FDA as class III pre-market-approval (PMA) devices. Several devices have received FDA PMA approval. Examples of these devices include, but are not limited to, the Precision Spinal Cord Stimulator System and the Genesis IPG System. Systems with external transmitters are regulated by the FDA as Class II Section 510(k) devices. The FDA granted Section 510(k) approval for Advanced Neuromodulation Systems to market its Renew SCS, to Medtronic to market its Spinal Cord and Peripheral Nerve Stimulation Systems, and to Micronet Medical, Inc. to market its Axxess Spinal Cord Stimulation Lead. St. Jude Medical has also received FDA approval for its Protege MRI spinal cord stimulation system.

High-Frequency Stimulation

Nevro (Menlo Park, Calif) gained FDA approval in May 2015 for its Senza SCS system, intended for chronic pain treatment. The device administers the company's HF10 therapy in the trunk and/or limbs, which treats unilateral or bilateral pain related to FBSS, intractable low-back pain, and leg pain. The therapy is the only SCS therapy that is FDA-indicated to alleviate pain without paresthesia (a

constant tingling sensation associated with traditional spinal cord stimulation techniques).

In July 2021, the FDA expanded the PMA indications for Nevro's Senza SCS System when programmed to a frequency of 10k Hz to aid in the management of chronic intractable pain of the lower limb(s) associated with diabetic neuropathy. A six-month RCT (Peterson et al., 2021) of 216 patients with painful diabetic neuropathy demonstrated significant improvement in mean VAS score, neurologic examination, and health-related quality of life scores in the SCS group compared to conventional medical management alone. Longer-term studies are needed to confirm durability of effect.

Burst Stimulation

In October 2016, the FDA approved BurstDR stimulation (St. Jude Medical), a clinician programmer application that provides intermittent "burst" stimulation for patients rather than at a constant ("tonic") rate. Burst stimulation is proposed to relieve pain with fewer paresthesia. The burst stimulation device works in conjunction with standard SCS devices. In February 2023, the FDA expanded the Indication for Use for Abbott's Prodigy, Proclaim, and Proclaim XR SCS Systems to includ treatment of diabetic peripheral neuropathy of the lower extremities through a series of consistent stimulation pulses, called the tonic stimulation mode.

Dorsal Root Ganglion Stimulation

Abbott Medical has several devices with FDA approval, including the Axium and Proclaim DRG neurostimulator system for the treatment of moderate to severe chronic intractable pain of the lower limbs in adult patients with Types I and II CRPS.

Peripheral Nerve Field Stimulation (PNFS)

There are no FDA-approved devices specifically for peripheral nerve field stimulation (PNFS).

Closed-Loop Spinal Cord Stimulation

The Evoke SCS System received FDA approval, on February 28, 2022, for the treatment of chronic intractable pain of the trunk and/or limbs including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain.

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
0784T	Insertion or replacement of percutaneous electrode array, spinal, with integrated neurostimulator, including imaging guidance, when performed

Code	Description
0785T	Revision or removal of neurostimulator electrode array, spinal, with integrated neurostimulator
63650	Percutaneous implantation of neurostimulator electrode array; epidural
63655	Laminectomy for implantation neurostimulator electrode, plate/paddle; epidural
63661	Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed
63662	Removal of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy when performed
63663	Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s) including fluoroscopy, when performed
63664	Revision including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver requiring pocket creation and connection between electrode array and pulse generator or receiver
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver

HCPCS Codes

Code	Description
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
C1827	Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller
L8679	Implantable neurostimulator pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension

Code	Description
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

ICD10 Codes

Code	Description
Multiple Codes	

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Electrical Nerve Stimulators (NCD 160.7) [accessed 2025 Feb 27]

Based on our review, peripheral nerve field stimulation (PNFS) is not addressed in National or Regional Medicare coverage determinations or policies.

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 (including Medicare HMO-Dual Special Needs Program (DSNP) 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.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION	
Committee Approval Dates	
11/15/01, 09/19/02, 09/18/03, 07/15/04, 07/21/05, 05/18/06, 04/19/07, 06/19/08, 05/28/09, 04/22/10, 03/17/11, 03/15/12, 06/19/14, 08/20/15, 10/20/16, 10/19/17, 06/21/18, 12/20/18, 06/20/19, 08/20/20, 04/15/21, 09/16/21, 05/19/22, 05/18/23, 10/17/24, 06/26/25	
Date	**Summary of Changes**
06/26/25	• Annual review, policy intent unchanged. Revised conservative treatment criteria.
01/01/25	• Summary of changes tracking implemented.
11/15/01	• Original effective date