PREMERA HMO

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MEDICAL POLICY – 7.01.546

Spinal Cord and Dorsal Root Ganglion Stimulation

BCBSA Ref. Policy: 7.01.25

Effective Date:	**Nov. 7, 2025***
Last Revised	Jul. 8, 2025
Replaces:	7.01.25
*This policy has been revised. Click o view the current policy.	

RELATED MEDICAL POLICIES:

1.01.507	Electrical Stimulation Devices
7.01.63	Deep Brain Stimulation
7.01.574	Implantable Peripheral Nerve Stimulation for the Treatment of Chronic Pain and Other Conditions
11.01.525	Site of Service Ambulatory Service Center (ASC) Select Surgical Procedures

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POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Spinal cord stimulation is used to treat certain types of pain. A small device is surgically placed beneath the skin. Small amounts of electric current are sent to the spinal cord and the current interferes with the sensation of pain. This treatment has been studied for use in several different types of pain. Medical studies show that spinal cord stimulation may be effective to treat low back pain when surgery and other treatments have not helped. Medical evidence also shows it may be effective for certain other types of pain including complex regional pain syndrome. This policy discusses when spinal cord stimulation and dorsal root ganglion stimulation may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

We will review for medical necessity these elective surgical procedures.

We also will review the site of service for medical necessity. Site of service is defined as the location where the surgical procedure is performed, such as an off campus-outpatient hospital or medical center, an on campus-outpatient hospital or medical center, an ambulatory surgical center, or an inpatient hospital or medical center.

Site of Service for Elective Surgical Procedures	Medical Necessity
Medically necessary sites of service: • **Ambulatory Surgical Center**	**Certain elective surgical procedures will be covered in the most appropriate, safe, and cost-effective site. This is the preferred medically necessary site of service for certain elective surgical procedures.**

• **Off campus-outpatient hospital/medical center**
• **On campus-outpatient hospital/medical center**
	Certain elective surgical procedures will be covered in the most appropriate, safe, and cost-effective site. An elective surgical procedure performed in a hospital outpatient department may be considered medically necessary if there is no access to an ambulatory surgical center due to one of the following criteria:
	• There is no qualifying ASC within 30 miles that can provide the necessary care due to one of the following:
	  ○ There is no geographically accessible ASC that has the necessary equipment to perform the procedure; or
	  ○ There is no geographically accessible ASC available at which the individual's physician has privileges; or
	  ○ An ASC's specific guideline prohibits the use of the ASC related to the individual's health condition or weight, or
	• Individual is aged 18 or younger, or
	• The service being performed is in conjunction with an additional service that requires the use of a hospital outpatient department, and the procedures are being performed in the same operative session
	OR
	• Individual has a clinical condition which puts them at increased risk for complications including any of the following (this list may not be all inclusive):
	  ○ **Anesthesia Risk**

Site of Service for Elective Surgical Procedures	Medical Necessity
	▪ ASA classification III or higher (see **definition**) ▪ Personal history of complication of anesthesia ▪ Documentation of alcohol dependence or history of cocaine use ▪ Prolonged surgery (greater than 3 hours) ○ **Cardiovascular Risk** ▪ Uncompensated chronic heart failure (**NYHA class** III or IV) ▪ Recent history of myocardial infarction (MI) (less than 3 months) ▪ Poorly controlled, resistant hypertension* ▪ Recent history of cerebrovascular accident (< 3 months) ▪ Increased risk for cardiac ischemia (drug eluting stent placed less than 1 year or angioplasty less than 90 days) ▪ Symptomatic cardiac arrhythmia despite medication ▪ Significant valvular heart disease ○ **Liver Risk** ▪ Advance liver disease (MELD Score greater than 8)** ○ **Pulmonary Risk** ▪ Chronic obstructive pulmonary disease (COPD) (FEV1 less than 50%) ▪ Poorly controlled asthma (FEV1 less than 80% despite treatment) ▪ Moderate to severe obstructive sleep apnea (OSA)*** ○ **Renal Risk** ▪ End stage renal disease (on dialysis) ○ **Other** ▪ Morbid obesity (BMI greater than or equal to 50) ▪ Pregnancy ▪ Bleeding disorder (requiring replacement factor, blood products, or special infusion product [DDAVP**** does not meet this criterion]) ▪ Anticipated need for transfusion(s)

Site of Service for Elective Surgical Procedures	Medical Necessity
	Note: * 3 or more drugs to control blood pressure ** https://reference.medscape.com/calculator/meld-score-end-stage-liver-disease *** Moderate-AHI greater than or equal to 15 and less than or equal to 30, Severe-AHI greater than or equal to 30 ****DDAVP-Deamino-Delta-D-Arginine Vasopressin (Desmopressin)
• **Off campus-outpatient hospital/medical center** • **On campus-outpatient hospital/medical center**	**This site of service is considered not medically necessary for certain elective surgical procedures when the site of service criteria listed above are not met.**
• **Inpatient hospital**	**This site of service is considered not medically necessary for this elective surgical procedure.**

Procedure	Medical Necessity
Spinal cord stimulation trial and permanent placement • **Standard spinal cord stimulation** • **High-frequency spinal cord stimulation**	**A trial with standard or high-frequency spinal cord stimulation using a temporary stimulator may be considered medically necessary when ALL of the following criteria are met:** • The treatment is used only as a last resort. Other treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) have failed, or are judged to be unsuitable or contraindicated **AND** • The individual has severe and chronic neuropathic pain of the trunk or limbs resulting from actual damage to peripheral nerves (such as failed lumbar back surgery syndrome, complex regional pain syndrome, arachnoiditis, phantom limb/stump pain, peripheral neuropathy, or painful diabetic neuropathy) **AND** • Member has obtained clearance by a licensed psychologist, psychiatrist, or other licensed mental health professional **AND** • No untreated drug habituation exists **Placement of a permanent spinal cord stimulator may be considered medically necessary when the above medical**

Procedure	Medical Necessity
	necessity criteria for a trial spinal cord stimulator are met, and there is demonstration of at least a 50% reduction in pain with at least a 3-day trial of temporary spinal cord stimulation
Dorsal root ganglion (DRG) stimulation trial and permanent placement	**A dorsal root ganglion neurostimulation trial is considered medically necessary for the treatment of severe and chronic pain of the trunk or limbs that is refractory to all other pain therapies when ALL of the following criteria are met:** • The treatment is used only as a last resort. Other treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) have failed, or are judged to be unsuitable or contraindicated **AND** • The individual has severe and chronic neuropathic pain of the trunk or limbs resulting from actual damage to peripheral nerves (such as failed lumbar back surgery syndrome, complex regional pain syndrome, arachnoiditis, phantom limb/stump pain, peripheral neuropathy, or painful diabetic neuropathy) **AND** • Member has obtained clearance by a licensed psychologist, psychiatrist or other licensed mental health professional **AND** • No untreated drug habituation exists **Placement of a permanent dorsal root ganglion neurostimulator may be considered medically necessary when the above medical necessity criteria for a trial dorsal root ganglion neurostimulator are met, and there is demonstration of at least a 50% reduction in pain with at least a 3-day trial of temporary dorsal root ganglion stimulation**
Replacement of spinal cord stimulators or dorsal root ganglion neurostimulators	**Replacement of an existing spinal cord stimulator (standard or high-frequency) or dorsal root ganglion neurostimulator may be considered medically necessary in only a small subset of individuals when:** • The stimulator is not working or is broken **OR** • Replacement is needed because the individual's condition has changed such that the current processor is inadequate or no

Procedure	Medical Necessity
	longer meets the functional needs of the individual and improvement is expected with a replacement device. **Replacement of a functioning standard spinal cord stimulator with a high-frequency spinal cord stimulator is considered not medically necessary.**

Procedure	Investigational
Spinal cord stimulation in other situations	**Spinal cord stimulation is considered investigational in all other situations not outlined in the Medical Necessity section above, including but not limited to treatment of any of the following:** • Central deafferentation pain (pain related to CNS damage from a stroke or spinal cord injury) • Nociceptive pain (pain resulting from irritation rather than damage to the nerves (see **Definition of Terms**) • Critical limb ischemia as a technique to forestall amputation • Refractory angina pectoris • Chronic pelvic pain (abdominal or visceral) • Treatment of cancer-related pain • Treatment of heart failure

Documentation Requirements

The individual's medical records submitted for review should document that medical necessity criteria are met. The record should include ALL of the following:

- For TRIAL spinal cord stimulator or dorsal root ganglion neurostimulator
  - Relevant history and physical showing that the individual has severe and chronic neuropathic pain of the trunk or limbs resulting from actual damage to peripheral nerves
  - That the treatment is used only as a last resort, that individual has tried other standard treatment modalities and they were not effective or contraindicated
  - Individual has obtained clearance from a licensed psychologist, licensed psychiatrist, or other licensed mental health professional
  - The individual has no untreated drug habituation
- For PERMANENT spinal cord stimulator or dorsal root ganglion neurostimulator:
  - All of the above listed criteria are met

Documentation Requirements

AND

- There is demonstration of at least a 50% reduction in pain with at least a 3-day trial of temporary spinal cord stimulation or dorsal root ganglion neurostimulation.

Coding

Code	Description
CPT	
0784T	Insertion or replacement of percutaneous electrode array, spinal, with integrated neurostimulator, including imaging guidance, when performed
0785T	Revision or removal of neurostimulator electrode array, spinal, with integrated neurostimulator
63650	Percutaneous implantation of neurostimulator electrode array, epidural
63655	Laminectomy for implantation of neurostimulator electrodes, 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, direct or inductive coupling
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver
HCPCS	
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system

Code	Description
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
C1826	Generator, neurostimulator (implantable), includes closed feedback loop leads and all implantable components, with rechargeable battery and charging system
C1827	Generator, neurostimulator (implantable), nonrechargeable, with implantable stimulation lead and external paired stimulation controller
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
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only

Related Information

"Burst" neurostimulation is an alternate programming of a standard SCS device. A clinician programmer application is used to configure a standard SCS device to provide stimulation in "bursts" rather than at a constant ("tonic") rate.

The optimal level for spinal cord stimulator lead position depends on the location of pain. For low back and lower extremity pain, leads are placed at low thoracic/upper lumbar levels (T8 to L1). Cervical leads, which are placed for treatment of pain related to cervical radicular pain or upper extremity complex regional pain syndrome (CRPS), may be accessed via the mid-to upper-thoracic epidural space.

The usual levels for lead position for pain in anatomic regions are as follows:

- Neck – Above C3
- Shoulder – Above C5
- Hand – C5, C6
- Thigh – Anterior T7, T8, posterior T11 to L1
- Foot – L1
- Low back – T9 to T10

Definition of Terms

American Society of Anesthesiologists (ASA) Score:

ASA 1 A normal healthy patient.
ASA 2 A patient with mild systemic disease.
ASA 3 A patient with severe systemic disease.
ASA 4 A patient with severe systemic disease that is a constant threat to life.
ASA 5 A moribund patient who is not expected to survive

Arachnoiditis: An inflammation of the arachnoid, one of the linings (meninges) that surround the nerves of the brain and spinal cord, leading to disabling pain, numbness, burning and stinging like symptoms. These symptoms commonly occur in the lower back and lower extremities and may be progressive over time. It is considered a rare disorder.

Central deafferentation pain: Pain caused by a primary lesion or dysfunction of the central nervous system such as cerebrovascular lesions, multiple sclerosis or traumatic spinal cord

injuries leading to a chronic burning, shooting pain, numbness or tingling within the affected body part. There may also be related sensitivity to touch as well as to temperature.

Complex Regional Pain Syndrome (CRPS): CRPS is a chronic pain condition that is thought to be caused by damage to the peripheral (nerve signaling from the brain and spinal cord to the rest of the body) and central nervous systems (the brain and spinal cord). It usually affects one limb (arm, leg, hand, or foot) often after an injury or trauma. The symptoms are excessive pain, increased sensitivity in the affected area, and may include changes in skin temperature, skin color, or swelling of the affected limb. There are two types: CRPS I (previously known as reflex sympathetic dystrophy syndrome) describes individuals without a confirmed nerve injury. CRPS II (previously known as causalgia) describes individuals with a confirmed nerve injury.

Neuropathic pain: Neuropathic pain is caused by problems with or damage to the somatosensory nervous system itself. For example, a herniated disc can compress a nerve entering the spinal cord, or phantom nerve pain can happen after a limb has been amputated. Neuropathic pain tends to be shooting or burning pain and is often chronic. Physical signs of nerve damage may be seen on examination. Placement of a spinal cord stimulator is only appropriate for the treatment of neuropathic pain.

New York Heart Association (NYHA) Classification:

Class I No symptoms and no limitation in ordinary physical activity, e.g., shortness of breath when walking, climbing stairs etc.
Class II Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
Class III Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g., walking short distances (20–100 m). Comfortable only at rest.
Class IV Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients

Nociceptive Pain: Nociceptive pain happens after tissue in the body has been damaged or is inflamed. Nociceptors (pain receptors) in the tissue may be stimulated by noxious chemicals, mechanical trauma, or heat. This stimulation causes the nociceptors to fire and send an electrical signal up a sensory nerve to the brain, and the sensation of pain is felt. Nociceptive pain tends to happen suddenly, such as when a finger is cut with a knife, and the pain stops once the damage has healed.

Evidence Review

Description

Spinal cord stimulation (SCS) delivers low-voltage electrical stimulation to the dorsal columns of the spinal cord to block the sensation of pain; this is achieved through a surgically implanted SCS device, which comes equipped with a radiofrequency receiver. The neurostimulator device is also issued with a standard power source (battery) that can be implanted or worn externally. Other neurostimulators target the dorsal root ganglion.

Background

Chronic Pain

Spinal cord stimulation (SCS) has been used in a wide variety of chronic refractory pain conditions, including pain associated with cancer, failed back pain syndromes, arachnoiditis, and complex regional pain syndrome (CPRS; i.e., chronic reflex sympathetic dystrophy). There has also been interest in SCS as a treatment of critical limb ischemia, primarily in individuals who are poor candidates for revascularization and in individuals with refractory chest pain.

Spinal Cord Stimulation

SCS—also called dorsal column stimulation—involves the use of low-level epidural electrical stimulation of the spinal cord dorsal columns. The neurophysiology of pain relief after SCS is uncertain but may be related to either activation of an inhibitory system or blockage of facilitative circuits.

SCS devices consist of several components: 1) the lead that delivers the electrical stimulation to the spinal cord; 2) an extension wire that conducts the electrical stimulation from the power source to the lead; and 3) a power source that generates the electricity. The lead may incorporate from four to eight electrodes, with eight electrodes more commonly used for complex pain patterns. There are two basic types of power source: one type, the power source (battery) can be surgically implanted or worn externally with an antenna over the receiver; the other, a radiofrequency receiver, is implanted. Totally implantable systems are most commonly used.

The individual's pain distribution pattern dictates at what level of the spinal cord the stimulation lead is placed. The pain pattern may influence the type of device used. For example, a lead with

eight electrodes may be selected for those with complex pain patterns or bilateral pain. Implantation of the spinal cord stimulator is typically a 2-step process. Initially, the electrode is temporarily implanted in the epidural space, allowing a trial period of stimulation. Once treatment effectiveness is confirmed (defined as at least 50% reduction in pain), the electrodes and radio-receiver/transducer are permanently implanted. Successful SCS may require extensive programming of the neurostimulators to identify the optimal electrode combinations and stimulation channels.

Dorsal Root Ganglion Neurostimulation

Dorsal root ganglion neurostimulation (or dorsal root ganglion stimulation, DRGS) uses the same epidural approach technique as spinal cord stimulation but targets a different anatomical target, the dorsal root ganglion. Dorsal root ganglia, situated within the spine as clusters of nerve cell bodies, serve as the "sensory gate" for pain signals entering the spinal cord. DRGS seeks to modulate the activity of these nerve cell bodies, potentially intercepting or diminishing pain signals before they reach the spinal cord. DRGS proves particularly efficacious for localized or chronic nerve pain conditions, such as complex regional pain syndrome, post-amputation pain, and pain following specific surgical procedures. It allows for more precise targeting of specific nerves and pain areas compared to SCS, potentially leading to better pain relief with fewer side effects. Moreover, DRGS may induce less paresthesia (tingling or numbness) than SCS, owing to its focused and precise stimulation. Recovery from DRGS implantation typically spans 6-8 weeks, during which individuals are advised to refrain from strenuous activities.

Traditional SCS devices use electrical stimulation with a frequency of 100 to 1000 Hz. High frequency devices use electrical stimulation with a frequency of 10,000 Hz. In 2016, the US Food and Drug Administration (FDA) approved a clinician programmer application that allows a SCS device to provide stimulation in bursts rather than at a constant rate. Burst stimulation is proposed to relieve pain with fewer paresthesias. The burst stimulation device works in conjunction with standard SCS devices. With the newly approved app, stimulation is provided in five, 500-Hz burst spikes at a rate of 40 Hz, with a pulse width of 1 ms. Other neurostimulators target the dorsal root ganglion.

Summary of Evidence

Treatment-Refractory Chronic Pain

For individuals who have treatment-refractory chronic pain of the trunk or limbs who receive standard SCS, the evidence includes systematic reviews and randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Available RCTs are heterogeneous regarding underlying diagnoses in select patient populations. However, the trials including individuals with underlying neuropathic pain processes have shown a significant benefit with SCS. Systematic reviews have supported the use of SCS to treat refractory trunk or limb pain, and individuals who have failed all other treatment modalities have few options. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have treatment-refractory chronic pain of the trunk or limbs who receive HFSCS, the evidence includes systematic reviews and RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Two RCTs that enrolled participants not previously treated with spinal cord stimulation reported clinically and statistically significant benefits associated with high-frequency spinal cord stimulation. Another RCT in individuals who had chronic pain despite previous treatment with standard SCS found no benefit for those receiving high-frequency stimulation compared with sham-control; however, it is difficult to compare these findings with other trials of SCS due to the different patient populations, short treatment periods, and the crossover period effect. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have treatment-refractory chronic pain of the trunk or limbs who receive dorsal root ganglion (DRG) neurostimulation, the evidence includes systematic reviews, an RCT, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The unblinded RCT found that individuals receiving DRG neurostimulation had significantly higher rates of treatment success (physical functioning score and quality of life measures), at 3 and 12 months compared with those receiving standard SCS devices. DRG neurostimulation was found to be noninferior to SCS in the percentage achieving≥50% pain reduction, emotional functioning score, and 36-Item Short-Form Health Survey scores. Both groups experienced paresthesias but individuals in the DRG group reported less postural variation in paresthesia and reduced extraneous stimulation in nonpainful areas. Rates of serious adverse events were similar between the two study arms. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Critical Limb Ischemia

For individuals who have critical limb ischemia who receive SCS, the evidence includes systematic reviews of several small RCTs. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. In pooled analyses, SCS was associated with a lower risk of amputation versus control, but results were not consistently statistically significant due to differences in methodologies. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Treatment-Refractory Angina Pectoris

For individuals who have treatment-refractory angina pectoris who receive SCS, the evidence includes systematic reviews and RCTs. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. Numerous small RCTs have evaluated SCS as a treatment for refractory angina. While some have reported benefits, most have not. In two recent RCTs, there was no significant benefit in the primary outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Heart Failure

For individuals who have heart failure who receive spinal cord stimulation, the evidence includes a systematic review. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. Four studies (including two RCTs) with a total of 125 patients were selected. Two studies reported improvements in New York Heart Association classification, and quality of life parameters, while only one study showed positive changes in left ventricular ejection function and VO2 max. No studies found significant changes in NT-proBNP (N-terminal Pro-Brain Natriuretic Peptide) following SCS therapy. Discrepancies in results could be due to methodological variations and induction technique diversity. Further studies are needed to develop a solid approach for employing SCS in heart failure patients.

Cancer-Related Pain

For individuals who have cancer-related pain who receive SCS, the evidence includes case series. Relevant outcomes are symptoms, functional outcomes, medication use, and treatment-related morbidity. No RCTs evaluating SCS in this population were identified. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05466110	sPinal coRd stimulatiOn coMpared With Lumbar InStrumEntation for Low Back Pain After Previous Lumbar Decompression (PROMISE): a Prospective Randomized Controlled Study	84	May 2025
NCT04915157	Efficacy of Spinal Cord Stimulation in Patients With Refractory Angina Pectoris; a Randomized Controlled Trial	72	Jun 2025
NCT05372822	Spinal Cord Burst Stimulation for Chronic Radicular Pain Following Lumbar Spine Surgery: A Randomized Double-blind Sham-controlled Crossover Trial	50	Aug 2025
NCT03681262	Comparing Long-Term Effectiveness of High Frequency and Burst Spinal Cord Stimulation	7	Dec 2026

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Association of Clinical Endocrinology

In 2022, the American Association of Clinical Endocrinology published evidence-based recommendations for the care of individuals with diabetes mellitus.[89]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 DPN [diabetic peripheral neuropathy]'. The evidence for the statement was rated as Grade B [Strong]; BEL [best evidence level] 1 [Randomized controlled trial; Meta-analysis of only randomized controlled trials].

American Society of Regional Anesthesia and Pain Medicine

In 2023, American Society of Regional Anesthesia and Pain Medicine published evidence-based consensus guidelines on patient selection and trial stimulation for SCS therapy for chronic non-cancer pain.[90] Recommendations included that SCS trial should be performed before a definitive SCS implant except in anginal pain (grade B). All patients must be screened with an objective validated instrument for psychosocial factors, and this must include depression (grade B). Despite some limitations, a trial helps patient selection and provides patients with an opportunity to experience the therapy. These recommendations are expected to guide practicing physicians and other stakeholders and should not be mistaken as practice standards. Physicians should continue to make their best judgment based on individual patient considerations and preferences.

American Society of Interventional Pain Physicians

In 2013, the American Society of Interventional Pain Physicians updated its evidence-based guidelines on interventional techniques for the management of chronic spinal pain.[91] The guidelines included a statement that there is fair evidence for the following recommendation for SCS: "SCS is indicated in chronic low back pain with lower extremity pain secondary to failed

back surgery syndrome (FBSS), after exhausting multiple conservative and interventional modalities". No updates have been made since the original publication.

American Society of Pain and Neuroscience

The American Society of Pain and Neuroscience issued a comprehensive guideline in 2021 on the management of cancer-related pain.[92] The guideline found that spinal cord stimulation may be considered for 1) treatment of refractory cancer pain (Level II-3-C evidence: multiple series compared over time, with or without intervention, and surprising results in noncontrolled experience; treatment is neither recommendable nor inadvisable), and 2) on a case-by-case basis for "pain that is related to cancer treatment such as chemotherapy-induced peripheral neuropathy" (level III-C evidence: clinical experiences-based opinions, descriptive studies, clinical observations, or reports of expert committee; treatment is neither recommendable nor inadvisable).

The American Society of Pain and Neuroscience published consensus guidelines on interventional therapies for knee pain in 2022.[93] The guidelines state that "Chronic pain that is refractory to acute treatment is managed by progressing to spinal cord stimulator, dorsal root ganglion stimulator, or botulinum toxin (Botox) injection." They also include the statement that "DRG [Dorsal Root Ganglion Stimulation] is a safe and effective treatment option for chronic post-surgical and focal neuropathic pain of the knee (i.e., complex regional pain syndrome [CRPS]); Level I, Grade A, Consensus Strong."

The American Society of Pain and Neuroscience published consensus guidelines on interventional therapies for back pain in 2022.[94] The guideline recommendations for spinal cord stimulation are summarized in **Table 2** below.

Table 2. American Society of Pain and Neuroscience Recommendations for Spinal Cord Stimulation for Back Pain

Recommendation	Grade	Level of evidence	Level of certainty of net benefit
Following lumbar surgery	A	I-A	Strong
Treatment of non-surgical low back pain	B	I-C	Moderate
Treatment of lumbar spinal stenosis	C	I-C	Moderate

National Institute for Health and Care Excellence

In 2008, the NICE issued guidance on SCS for chronic pain of neuropathic or ischemic origin, which was reaffirmed in 2014.[95] The NICE recommended SCS as a treatment option for adults with chronic pain of neuropathic origin (measuring at least 50 mm on a 0-100 mm visual analog scale) that continues for at least 6 months despite appropriate conventional medical management, and who have had a successful trial of stimulation as part of an assessment by a specialist team.

In the same guidance, the NICE stated that SCS was not recommended for chronic pain of ischemic origin except in the context of research.

Medicare National Coverage

According to Medicare policy (Effective date 08/07/1995: Manual Section Number 160.7), the implantation of central nervous system stimulators may be covered as therapies for the relief of chronic intractable pain, subject to the following conditions:

- The implantation of the stimulator is used only as a late resort (if not a last resort) for individuals with chronic intractable pain;
- Other treatment modalities (pharmacological, surgical, physical, or psychological therapies) have been tried and did not prove satisfactory, or are judged to be unsuitable or contraindicated for the given individual;
- Individuals have undergone careful screening, evaluation, and diagnosis by a multidisciplinary team prior to implantation. (Such screening must include psychological, as well as physical evaluation.);
- All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment training, and follow-up of the individual must be available; and
- Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation.[96]

Regulatory Status

A large number of neurostimulator devices have been approved by the 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]) (Table 5). In October 2016, the FDA approved BurstDR stimulation (St. Jude Medical), a clinician programmer application that provides intermittent "burst" stimulation for individuals with certain St. Jude spinal cord stimulation devices.

Table 5. FDA Cleared or Approved Devices for Spinal Cord and Dorsal Root Ganglion Stimulation

Device	Manufacturer	Product code	Original clearance/ approval date	Original 510(k) or PMA number	Indication
Algovita Spinal Cord Stimulation System	Nuvectra Corporation	LGW	Nov 2015	P130028	Chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome, intractable low back pain, and leg pain.
Axium (1st generation) and Proclaim DRG (2nd generation) Neurostimulator System	Abbott Medical	PMP	Feb 2016	P150004	Moderate to severe chronic intractable pain of the lower limbs in adult patients with Types I and II CRPS

Device	Manufacturer	Product code	Original clearance/ approval date	Original 510(k) or PMA number	Indication
Cordis Programmable Neural Stimulator Models 900a	Cordis Corporation	LGW	Apr 1981[a]	P800040	Stimulator, Spinal-Cord, Totally Implanted For Pain Relief
Freedom SCS	Stimwave Technologies (now Curonix)	GZB	Aug 2016	K180981	Chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain
Genesis And Eon Family Neurostimulation (Ipg) System; Eterna Spinal Cord Stimulation (SCS) System; Prodigy, Proclaim, and Proclaim XR Spinal Cord Stimulation (SCS) Systems	St. Jude Medical/ Abbott Medical	LGW;QRB	Nov 2001	P010032	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 and leg pain, and diabetic peripheral neuropathy of the lower extremities.
Restore, Itrel, Synergy, Intellis, And Vanta Spinal Cord Stimulation Systems	Medtronic Neuromodulation	LGW	Nov 1984	P840001	Chronic, intractable pain of the trunk and/or limbs- including unilateral or bilateral pain

Device	Manufacturer	Product code	Original clearance/ approval date	Original 510(k) or PMA number	Indication
					associated with the following conditions: • Failed Back Syndrome (FBS) or low back syndrome or failed back • Radicular pain syndrome or radiculopathies resulting in pain secondary to FBS or herniated disk • Postlaminectomy pain • Multiple back operations • Unsuccessful disk surgery • Refractory Degenerative Disk Disease (DDD)/herniated disk pain • Peripheral causalgia • Epidural fibrosis • Arachnoiditis or lumbar adhesive arachnoiditis • Complex Regional Pain

Device	Manufacturer	Product code	Original clearance/ approval date	Original 510(k) or PMA number	Indication
					Syndrome (CRPS), Reflex Sympathetic Dystrophy (RSD), or causalgia • Diabetic peripheral neuropathy of the lower extremities
Precision SCS System	Boston Scientific Corporation	LGW	Apr 2004	P030017	Chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome, Types 1 and 2 CRPS, intractable low back pain and leg pain
Evoke SCS System	Saluda Medical Pty Ltd	LGW	Feb 2022	P190002	Chronic intractable pain of the trunk and/or limbs including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low

Device	Manufacturer	Product code	Original clearance/ approval date	Original 510(k) or PMA number	Indication
					back pain and leg pain.
Senza SCS System	Nevro Corporation	LGW	May 2015	P130022	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. When programmed to include a frequency of 10 kHz: Chronic intractable pain of the lower limbs, including unilateral or bilateral pain, associated with diabetic neuropathy; non-surgical refractory back pain (intractable back pain without prior surgery and not a candidate for back surgery)

Device	Manufacturer	Product code	Original clearance/ approval date	Original 510(k) or PMA number	Indication
Nalu Neurostimulation System	Nalu Medical, Inc	GZB	Mar 2019	K183047	Chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain
Prospera Spinal Cord Stimulation (SCS) System	Biotronik NRO, Inc	LGW	Mar 2023	P210037	Chronic, intractable pain in the trunk and/or limbs, which may include unilateral or bilateral pain, resulting from any of the following: 1) FBS or low back syndrome or failed back; 2) Radicular pain syndrome or radiculopathies resulting in pain secondary to FBS or; 3) Herniated disk; 4) Postlaminectomy pain; 5) Multiple back operations; 6) Unsuccessful disk surgery; 7) DDD/herniated disk pain refractory to conservative and surgical

Device	Manufacturer	Product code	Original clearance/ approval date	Original 510(k) or PMA number	Indication
					interventions; 8) Peripheral causalgia; 9) Epidural fibrosis;10) Arachnoiditis or lumbar adhesive arachnoiditis; and11) CRPS, RSD, or causalgia

CRPS: Complex regional pain syndrome; DDD: degenerative disk disease; FDS failed back syndrome; :PMA: premarket approval; RSD: reflex sympathetic dystrophy; SCS: spinal cord stimulation.

[a] Withdrawn in 2016[1]

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.[2] Between July 27, 2016 and July 27, 2020, the FDA received 107,728 medical device reports related to spinal cord simulators intended for pain including 497 associated with patient death, 77,937 with patient injury, and 29,924 with device malfunction. The most frequently reported patient problem codes were inadequate pain relief (28.1%), pain (15.2%), unexpected therapeutic effects (10.9%), infection (7.5%), and discomfort (5.9%). Additionally, the most frequently reported device problem codes were charging problems (11.2%), impedance (10.6%), migration (7.2%), battery problem (6.4%), and premature discharge of battery (4.2%). The FDA made the following recommendations for clinicians to consider:

- Conduct a trial stimulation as described in the device labeling to identify and confirm satisfactory pain relief before permanent implantation.
- Permanent spinal cord stimulation should only be implanted in individuals who have undergone and passed a stimulation trial.
- Providers typically perform a stimulation trial on an individual for 3 to 7 days, and success is usually defined by a 50% reduction in pain symptoms. Inform patients about the risks of serious side effects and what to expect during the trial stimulation.

- Before implantation of any spinal cord stimulation, discuss the benefits and risks of the different types of implants and other treatment options, including magnetic resonance imaging compatibility of the devices.
- Before implantation, provide individuals with the manufacturer's patient labeling and any other education materials for the device that will be implanted.
- Develop an individualized programming, treatment, and follow-up plan for spinal cord stimulation therapy delivery with each individual.
- Provide each individual with the name of the device manufacturer, model, and the unique device identifier of the implant received.

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History

Date	Comments
04/10/12	New policy replacing 7.01.25.
07/20/12	Clarification made to first policy statement; pain is defined in single nerve-root distribution change to lumbosacral nerve root distribution, as approved by MPC on April 10, 2012.
08/27/12	Update Related Policies – Add 7.01.20. Update Coding Section – ICD-10 codes are now effective 10/01/2014.
04/16/13	Replace policy. No change to policy statements. References 14, 18, 21, 22 added.
12/19/13	Update Related Policies. Remove 1.01.19 as it was archived.
07/14/14	Annual Review. Policy statement revised. Spinal cord stimulation may now be considered medically necessary for pain due to complex regional pain syndrome when criteria are met. "Lumbar" added as clarification to failed back surgery syndrome and criteria revised. Rationale extensively updated. References added.
03/31/15	Annual Review. Policy statements unchanged. Policy updated with literature review through December 2014. References 5. 6, 16 added. Remove ICD-9 codes 03.93, 03.94, 86.05, 86.09 and 86.94, along with associated ICD-10 codes; these do not suspend and are informational only.
05/27/15	Coding update; ICD-9 procedure code 86.96 added to policy; ICD-10 PCS codes adding per cross walk remediation.
01/29/16	Coding update. Added HCPCS code L8679.
05/01/16	Annual Review, approved April 12, 2016. Clarified policy statement adding, licensed mental health provider. No new references added.

Date	Comments
03/01/17	Coding Update. Removed CPT code 95973 as it was deleted as of 01/01/2016.
04/14/17	Policy moved into new format; no change to policy statements. Evidence Review section reformatted.
07/01/17	Interim Review, approved June 6, 2017. Minor update to Medically Necessary policy statement to include Demonstration of at least 50% pain relief with a temporarily implanted electrode that was placed at least 3 days before the permanent implantation. Added HCPCS code L8683.
08/25/17	Coding update, removed CPT codes 95970, 95971, and 95972.
10/01/17	Annual Review, approved September 12, 2017. Policy section updated with the inclusion of high-frequency stimulation, high frequency with burst, and dorsal root ganglion stimulators. Title changed to include dorsal root ganglion stimulators. New HCPCS codes added. Removed CPT codes 95970, 95971, and 95972. Replacement and upgrade device criteria added. References 13, 17, 19-25, 30 and 40 added.
02/01/18	Interim Review, approved January 16, 2018. Added levels for spinal cord stimulator lead placement for clarity. Modified policy statement for clarity regarding trial and permanent implantation of a SCS. Removed axial back pain, failed cervical and thoracic surgery, post herpetic neuralgia, occipital neuralgia, and peripheral neuropathy from the investigational indications and added treatment of cancer-related pain, treatment of heart failure and pelvic pain added to investigational indications. Reference added.
02/06/18	Coding update, removed HCPCS code C1822.
02/13/18	Minor update; updated Introduction section.
03/01/18	Note added that this policy has been revised. Added link to revised policy that will become effective June 1, 2018.
06/01/18	Minor update; removed note and link to updated policy. Surgery Site of Service criteria becomes effective.
07/01/18	Annual Review, approved June 22, 2018. Policy updated with literature review through February 2018; references 1-12, 18-19, 21, 34-35, and 40-42 added. Policy statements unchanged. Related Information section revised to add burst neurostimulation as an alternate programming of a standard SCS device.
05/01/19	Minor update, clarified Site of Service requirements.
07/01/19	Annual Review, approved June 11, 2019. Policy updated with literature review through March 2019; references added. The dorsal root ganglion (DRG) policy statement was changed from investigational to medically necessary: "Dorsal root ganglion neurostimulation is considered medically necessary for the treatment of severe and chronic pain of the trunk or limbs." Removed HCPCS code L8684.
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020 and replaced with InterQual criteria for dates of service on or after July 2, 2020.
07/02/20	Delete policy.

Date	Comments
11/01/20	Policy reinstated effective February 5, 2021, approved October 13, 2020. Policy updated with literature review through February 2020; references added. Policy statements unchanged. Added HCPCS C1767, C1778, C1787, C1820, C1822, C1883 and C1897.
07/01/21	Annual Review, approved June 1, 2021. Policy updated with literature review through March 11, 2021; references added. Policy statements unchanged.
07/01/22	Annual Review, approved June 27, 2022. Policy updated with literature review through February 16, 2022; references added. Policy statements unchanged except for minor clarification.
01/01/23	Coding update. Added new HCPC codes C1826 and C1827.
07/01/23	Annual Review, approved June 12, 2023. Policy updated with literature review through February 13, 2023; references added. Policy statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
01/01/24	Coding update. Added new CPT codes 0784T and 0785T.
07/01/24	Annual Review, approved June 24, 2024. Policy updated with literature review through February 27, 2024; references added. Policy statements unchanged.
07/01/25	Annual Review, approved June 23, 2025. Policy updated with literature review through March 12, 2025; references added. Policy statements unchanged.
08/01/25	Interim Review, approved July 8, 2025. Removed Related Policy 11.01.524 Site of Service: Select Surgical Procedures. The following policy changes are effective November 7, 2025, following 90-day provider notification. Added related policy 11.01.525 Site of Service Ambulatory Service Center (ASC) Select Surgical Procedures. Added Site of Service Ambulatory Service Center (ASC) Select Surgical Procedures criteria.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.