PREMERA | BLUE CROSS

MEDICAL POLICY – 7.01.546

Spinal Cord and Dorsal Root Ganglion Stimulation

BCBSA Ref. Policy: 7.01.25

Effective Date:	July 1, 2018
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RELATED MEDICAL POLICIES:

1.01.507	Electrical Stimulation Devices
7.01.20	Vagus Nerve Stimulation
7.01.63	Deep Brain Stimulation
7.01.125	Occipital Nerve Stimulation
8.03.01	Functional Neuromuscular Electrical Stimulation
11.01.524	Site of Service: Select Surgical Procedures

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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 prove that spinal cord stimulation is effective to treat low back pain when surgery and other treatments haven't helped. Medical evidence also shows it can be effective for certain other types of pain including complex regional pain syndrome. This policy discusses when spinal cord 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

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: • **Off campus-outpatient hospital/medical center** • **On campus-outpatient hospital/medical center** • **Ambulatory Surgical Center**	**Certain elective surgical procedures will be covered in the most appropriate, safe, and cost effective site. These are the preferred medically necessary sites of service for certain elective surgical procedures.**

Inpatient hospital/medical center	**Certain elective surgical procedures will be covered in the most appropriate, safe, and cost-effective site. This site is considered medically necessary only when the patient has a clinical condition which puts him or her at increased risk for complications including any of the following (this list may not be all inclusive):**
	• Anesthesia Risk
	  ○ ASA classification III or higher (see **definition**)
	  ○ Personal history of complication of anesthesia
	  ○ Documentation of alcohol dependence or history of cocaine use
	  ○ Prolonged surgery (>3 hours)
	• Cardiovascular Risk
	  ○ Uncompensated chronic heart failure (**NYHA class** III or IV)
	  ○ Recent history of myocardial infarction (MI) (<3 months)
	  ○ Poorly controlled, resistant hypertension*
	  ○ Recent history of cerebrovascular accident (< 3 months)
	  ○ Increased risk for cardiac ischemia (drug eluting stent placed < 1 year or angioplasty <90 days)
	  ○ Symptomatic cardiac arrhythmia despite medication
	  ○ Significant valvular heart disease
	• Liver Risk
	  ○ Advance liver disease (MELD Score > 8)**
	• Pulmonary Risk

Site of Service for Elective Surgical Procedures	Medical Necessity
	○ Chronic obstructive pulmonary disease (COPD) (FEV1 <50%) ○ Poorly controlled asthma (FEV1 <80% despite treatment) ○ Moderate to severe obstructive sleep apnea (OSA)*** • Renal Risk ○ End stage renal disease (on dialysis) • Other ○ Morbid obesity (BMI ≥ 50) ○ Pregnancy ○ Bleeding disorder (requiring replacement factor, blood products, or special infusion product [DDAVP**** does not meet this criteria]) ○ Anticipated need for transfusion(s) * 3 or more drugs to control blood pressure ** **https://reference.medscape.com/calculator/meld-score-end-stage-liver-disease** *** Moderate-AHI≥15 and ≤ 30, Severe-AHI ≥30 ****DDAVP-Deamino-Delta-D-Arginine Vasopressin (Desmopressin)
Inpatient 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.**

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 patient has severe and chronic neuropathic pain of the trunk or limbs resulting from actual damage to peripheral

Procedure	Medical Necessity
	nerves (such as failed lumbar back syndrome, complex regional pain syndrome, arachnoiditis, phantom limb/stump pain, or peripheral 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 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**
Replacement of spinal cord stimulators	**Replacement of an existing spinal cord stimulator (regular or high-frequency) may be considered medically necessary in only a small subset of patients when:** • The stimulator is not working or is broken **OR** • Replacement is needed because the patient's condition has changed such that the current processor is inadequate or no longer meets the functional needs of the patient 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	**Spinal cord stimulation is considered investigational in all situations not outlined in the Medical Necessity section above, including but not limited to treatment of:** • 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**)

Procedure	Investigational
	• 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
Dorsal root ganglion (DRG) stimulation	**DRG neurostimulation is considered investigational for treatment of severe and chronic pain of the trunk or limbs.**

Documentation Requirements

The patient'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:
  - Relevant history and physical showing that the patient 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 patient has tried other standard treatment modalities and were not effective or contraindicated
  - Patient has obtained clearance from a licensed psychologist, licensed psychiatrist, or other licensed mental health professional
  - The patient has no untreated drug habituation
- For PERMANENT spinal cord stimulator:
  - All of the above listed criteria 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

Coding

Code	Description
CPT	
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

Code	Description
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	
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
L8684	Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement
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, eg, 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, eg, 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 (ie, chronic reflex sympathetic dystrophy). There has also been interest in SCS as a treatment of critical limb ischemia, primarily in patients who are poor candidates for revascularization and in patients 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.

Spinal cord stimulation (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 electrical stimulation. The lead may incorporate from 4 to 8 electrodes, with 8 electrodes more commonly used for complex pain patterns, such as bilateral pain or pain extending from the limbs to the trunk. 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 patient's pain distribution pattern dictates at what level in the spinal cord the stimulation lead is placed. The pain pattern may influence the type of device used; for example, a lead with 8 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 spinal cord stimulation may require extensive programming of the neurostimulators to identify the optimal electrode combinations and stimulation channels.

Traditional SCS devices use electrical stimulation with a frequency of 100 to 1000 Hz. In 2015, an SCS device, using a higher frequency (10,000 Hz) than predicate devices was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. High-frequency stimulation is proposed to be associated with fewer paresthesias, which are a recognized effect of SCS. In addition, in 2016, FDA approved a clinician programmer application that allows an 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 (DRG). DRGs are located between spinal nerves and the spinal cord on the posterior root and are believed to play an important role in neuropathic pain perception. Two systems have received approval or clearance from FDA.

Outcome Measures

The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) group has provided recommendations for 4 core chronic pain outcome domains that should be included when selecting outcome measures for clinical trials of treatments for chronic pain: (1) pain intensity; (2) physical functioning; (3) emotional functioning; and (4) participant ratings of overall improvement.[1] IMMPACT has also suggested specific outcome measures to address these core domains and has proposed provisional benchmarks for identifying clinically important changes in these specific outcome measures (see **Table 1**).[2,3]

Table 1. Health Outcome Measures Relevant to Trials of Chronic Pain

Domain	Outcome Measure	Description	Clinically Meaningful Difference
Pain intensity			
	Numeric rating scale Verbal rating scale Visual analog scale	Rating of pain intensity on a scale of 0 (no pain) to 10 (pain as bad as you can imagine) or from 0 to 10 cm	Minimally important: 10%-20% decrease Moderately important: ≥30% decrease Substantial: ≥50% decrease[3]
Physical functioning			
	Disease specific	**Measures of the interference of pain with physical functioning**	
	Multidimensional Pain Inventory[4] Interference Scale	60 items, self-report 12 subscales: interference, support, pain severity, self-control, negative mood, punishing responses, solicitous responses, distracting responses, household chores, outdoor work, activities away from home, and social activities Items rated on 0- to 6-point scale Interference subscale score calculated by mean of subscale items	≥0.6-point decrease[3]
	Brief Pain Inventory[5] Interference Scale	7 items, self-report Measures intensity, quality, relief and interference of pain and patients' ideas of the causes of pain Mean of the 7 interference items can be used as a measure of pain interference	1-point decrease[3]
	Oswestry Disability Index[6]	Measures functional impairment due to lower back pain: 10 sections, self-report Sections: intensity of pain, lifting, ability to care for oneself, ability to walk, ability to sit, sexual function, ability to stand, social life, sleep quality, and ability to travel Each section is scored on a 0 to 5 scale with 5 indicating	10 points[7]

Domain	Outcome Measure	Description	Clinically Meaningful Difference
		the greatest disability Total score calculated by taking the mean of the section scores and multiplying by 100	
	General	**Generic measure of physical functioning**	
	36-Item Short Form Health Survey	Measure overall health status: 36 items, self-report 8 domains: physical function, physical role, general health, bodily pain, mental health, social function, vitality/fatigue, and emotional role Physical Component Summary and Mental Component Summary scores are aggregate scores that can be calculated Higher scores indicate better health status	5-10 points[8-10]
Emotional functioning			
	Beck Depression Inventory[11]	21 items, self-report Measures severity of current symptoms of depressive disorders Scores range from 0 to 63	≥5-point decrease[3]
	Profile of Mood States[12]	65 items, self-report Measures total mood disturbance with 6 subscales: tension, depression, anger, vigor, fatigue, and confusion Scores range from 0 to 200	≥10- to 15-point decrease[3]
Global rating of improvement			
	Patient Global Impression of Change	Single-item, self-rating 7-point scale ranging from 1 (very much worse) to 7 (very much improved)	Minimally important: minimally improved Moderately important: much improved Substantial: very much improved[3]

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 RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Available RCTs are mixed regarding underlying diagnoses in select patient populations. However, those trials including patients 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 patients who have failed all other treatment modalities have few options. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have treatment-refractory chronic pain of the trunk or limbs who receive high-frequency SCS, the evidence includes 3 RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. One RCT comparing high-frequency with standard SCS in patients who had not previously been treated with SCS found a clinically and statistically significant benefit associated with high-frequency SCS. Another RCT in patients 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 a meaningful 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 an RCT and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. One unblinded RCT found that patients receiving DRG neurostimulation had significantly higher rates of treatment success at 3 and 12 months than those receiving standard SCS devices. Both groups experienced paresthesias, but patients in the DRG group reported less postural variation in paresthesia and reduced extraneous stimulation in nonpainful areas. Patients in the DRG group also reported more reduction in interference with physical functioning and mood states. Rates of serious adverse events were similar. Given that DRG neurostimulation targets a different portion of the sensory pathway and anatomic location than standard SCS, replication is needed in a confirmatory RCT. The evidence is insufficient to determine the effects of the technology on health outcomes.

Critical Limb Ischemia

For individuals who have critical limb ischemia who receive SCS, the evidence includes RCTs. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. In some pooled analyses of these RCTs, SCS did not result in a significantly lower rate of amputation, although a systematic review and meta-analysis did report a significant difference. The evidence is insufficient to determine the effects of the technology on health outcomes.

Treatment-Refractory Angina Pectoris

For individuals who have treatment-refractory angina pectoris who receive SCS, the evidence includes 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 benefit, most have not. In 2 more recent RCTs, there was no significant benefit on the primary outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

Heart Failure

For individuals who have heart failure who receive SCS, the evidence includes RCTs. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. One small pilot crossover study (N=9) reported at least 1 adverse event in 2 patients with the device turned on and in 2 patients with the device turned off. A sham-controlled randomized trial (N=66) did not find significant differences between groups but might have been underpowered to do so. The evidence is insufficient to determine the effects of the technology on health outcomes.

Cancer-Related Pain

For individuals who have cancer-related pain who receive SCS, the evidence includes no RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and

treatment-related morbidity. No RCTs evaluating SCS in this population were identified. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in **Table 2**.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02514590[a]	Wireless High Frequency Spinal Cord Stimulation for Chronic Pain	80	Mar 2018
NCT02902796	Comparison of 1000 Hertz (Hz), Burst, and Standard Spinal Cord Stimulation in Chronic Pain Relief	22	Dec 2017
NCT02093793[a]	A Randomized Controlled Study to Evaluate the Safety and Effectiveness of the Precision Spinal Cord Stimulator System Adapted for High-Rate Spinal Cord Stimulation	406	Apr 2019
NCT03014583	Study Comparing Conventional, Burst and High Frequency (HF) Spinal Cord Stimulation (SCS) in Refractory Failed Back Surgery Syndrome (FBSS) Patients After a 32-contact Surgical Lead Implantation (MULTIWAVE)	28	Jul 2019
NCT03318172	High-Density Spinal Cord Stimulation for the Treatment of Chronic Intractable Pain Patients: A Prospective Multicenter Randomized Controlled, Double-blind, Crossover Exploratory Study With 6-m Open Follow-up	100	Jul 2019
NCT03228420	A Post-Market, Multicenter, Prospective, Randomized Clinical Trial Comparing 10 kHz Spinal Cord Stimulation (HF10™ Therapy) Combined With Conventional Medical Management to Conventional Medical Management Alone in the Treatment of Chronic, Intractable, Neuropathic Limb Pain	360	Aug 2020
Unpublished			
NCT02112474	The Pain Suppressive Effect of Alternative Spinal Cord Stimulation Frequencies	30	Nov 2016 (unknown)
NCT01697358[a]	Prospective, Randomized Study of Multicolumn Implantable Lead Stimulation for Predominant Low Back	278	June 2017

NCT No.	Trial Name	Planned Enrollment	Completion Date
	Pain[66]		(completed)

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

International Association for the Study of Pain

The International Association for the Study of Pain (2013) published recommendations on management of neuropathic pain.[62] The Association issued 2 recommendations on SCS; both were considered weak due to the amount and consistency of the evidence. The recommendations supported the use of SCS for failed back surgery syndrome (FBSS) and for complex regional pain syndrome (CRPS).

American Society of Interventional Pain Physicians

The American Society of Interventional Pain Physicians (2013) updated its evidence-based guidelines for interventional techniques in the management of chronic spinal pain.[63] The guidelines included a statement that there is fair evidence in support of SCS in managing patients with failed back surgery syndrome.

Earlier evidence-based guidelines (2007) from the Society found the evidence for SCS in failed back surgery syndrome and complex regional pain syndrome strong for short-term relief and moderate for long-term relief.[64] Reported complications with SCS ranged from infection, hematoma, nerve damage, lack of appropriate paresthesia coverage, paralysis, nerve injury, to death.

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (2008) issued guidance on SCS for chronic pain of neuropathic or ischemic origin.[24] The Institute 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.

Medicare National Coverage

According to Medicare policy, 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 patients 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 patient;
- Patients 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 patient must be available; and
- Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation.[65]

Regulatory Status

A large number of neurostimulator devices, some used for spinal cord stimulation (SCS), have been approved by the FDA through the premarket approval process. Examples of fully implantable SCS devices approved through the premarket approval process include the Cordis programmable neurostimulator (Cordis Corp), approved in 1981; the Itrel® (Medtronic), approved in 1984; the Genesis and Eon devices (St. Jude Medical) approved in 2001; and the Precision Spinal Cord Stimulator (Advanced Bionics), approved in 2004. FDA product code: LGW.

In 2015, the Nevro Senza™ Spinal Cord Stimulator (Nevro Corp.), a totally implantable neurostimulator device, was approved by FDA for the following indications: "chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the

following: failed back surgery syndrome (FBSS), intractable low back pain, and leg pain."[13] This device uses a higher frequency of electrical stimulation (10 kHz) than standard devices.

In February 2016, the Axium Neurostimulator System (Spinal Modulation) was approved by FDA through the premarket approval process. This implanted device stimulates the dorsal root ganglion. Further, it is indicated as an aid in the management of moderate-to-severe intractable pain of the lower limbs in adults with complex regional pain syndrome types I and II.

In August 2016, the Freedom Spinal Cord Stimulator (Stimwave Technologies), a wireless injectable stimulator, was cleared for marketing by FDA through the 510(k) process for treating chronic, intractable pain of the trunk and/or lower limbs. The Freedom device has implantable or injectable microstimulators that contain electrode(s). The microstimulators with electrodes are powered by a wireless battery pack worn externally . The device can be placed to target the spinal cord (ie, levels T7 to L5) or to target the dorsal root ganglion.

In October 2016, FDA approved BurstDR™ stimulation (St. Jude Medical), a clinician programmer application that provides intermittent "burst" stimulation for patients with certain St. Jude SCS devices.

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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.
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.

Date	Comments
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.

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この通知には重要な情報が含まれています。この通知には、Premera Blue Cross の申請または補償範囲に関する重要な情報が含まれている場合があります。この通知に記載されている可能性がある重要な日付をご確認ください。健康保険や有料サポートを維持するには、特定の期日までに行動を取らなければならない場合があります。ご希望の言語による情報とサポートが無料で提供されます。800-722-1471 (TTY: 800-842-5357)までお電話ください。

한국어 (Korean):
본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관하여 그리고 Premera Blue Cross 를 통한 커버리지에 관한 정보를 포함하고 있을 수 있습니다. 본 통지서에는 핵심이 되는 날짜들이 있을 수 있습니다. 귀하는 귀하의 건강 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하는 이러한 정보와 도움을 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357) 로 전화하십시오.

ລາວ (Lao):
ແຈ້ງການນີ້ມີຂໍ້ມູນສຳຄັນ. ແຈ້ງການນີ້ອາດຈະມີຂໍ້ມູນສຳຄັນກ່ຽວກັບຄຳຮ້ອງສະໝັກ ຫຼື ຄວາມຄຸ້ມຄອງປະກັນໄພຂອງທ່ານຜ່ານ Premera Blue Cross. ອາດຈະມີວັນທີສຳຄັນໃນແຈ້ງການນີ້. ທ່ານອາດຈະຈຳເປັນຕ້ອງດຳເນີນການຕາມກຳນົດເວລາສະເພາະເພື່ອຮັກສາຄວາມຄຸ້ມຄອງປະກັນສຸຂະພາບ ຫຼື ຄວາມຊ່ວຍເຫຼືອເລື່ອງຄ່າໃຊ້ຈ່າຍຂອງທ່ານໄວ້. ທ່ານມີສິດໄດ້ຮັບຂໍ້ມູນນີ້ ແລະ ຄວາມຊ່ວຍເຫຼືອເປັນພາສາຂອງທ່ານໂດຍບໍ່ເສຍຄ່າ. ໃຫ້ໂທຫາ 800-722-1471 (TTY: 800-842-5357).

ភាសាខ្មែរ (Khmer):
សេចក្តីជូនដំណឹងនេះមានព័ត៌មានយ៉ាងសំខាន់។ សេចក្តីជូនដំណឹងនេះប្រហែលជាមានព័ត៌មានយ៉ាងសំខាន់អំពីទម្រង់បែបបទ ឬការរ៉ាប់រងរបស់អ្នកតាមរយៈ Premera Blue Cross ។ ប្រហែលជាមាន កាលបរិច្ឆេទសំខាន់នៅក្នុងសេចក្តីជូនដំណឹងនេះ។ អ្នកប្រហែលជាត្រូវការបញ្ចេញសមត្ថភាព ដល់កំណត់ថ្ងៃជាក់ច្បាស់នានា ដើម្បីនឹងរក្សាទុកការជានាវ៉ាប់រងសុខភាពរបស់អ្នក ឬប្រាក់ជំនួយចេញផ្លែ។ អ្នកមានសិទ្ធិទទួលព័ត៌មាននេះ និងជំនួយនៅក្នុងភាសារបស់អ្នកដោយមិនអស់លុយឡើយ។ សូមទូរស័ព្ទ 800-722-1471 (TTY: 800-842-5357)។

ਪੰਜਾਬੀ (Punjabi):
ਇਸ ਨੋਟਿਸ ਵਿਚ ਖਾਸ ਜਾਣਕਾਰੀ ਹੈ. ਇਸ ਨੋਟਿਸ ਵਿਚ Premera Blue Cross ਵਲੋਂ ਤੁਹਾਡੀ ਕਵਰੇਜ ਅਤੇ ਅਰਜੀ ਬਾਰੇ ਮਹੱਤਵਪੂਰਨ ਜਾਣਕਾਰੀ ਹੋ ਸਕਦੀ ਹੈ . ਇਸ ਨੋਜਿਸ ਜਵਚ ਖਾਸ ਤਾਰੀਖਾ ਹੋ ਸਕਦੀਆਂ ਹਨ. ਜੇਕਰ ਤੁਸੀ ਜਸਹਤ ਕਵਰੇਜ ਰਿੱਖਣੀ ਹੋਵੇ ਜਾ ਓਸ ਦੀ ਲਾਗਤ ਜਵਿੱਚ ਮਦਦ ਦੇ ਇਛੁੱਕ ਹੋ ਤਾਂ ਤੁਹਾਨੂੰ ਅੰਤਮ ਤਾਰੀਖ਼ ਤੋਂ ਪਹਿਲਾਂ ਕੁੱਝ ਖਾਸ ਕਦਮ ਚੁੱਕਣ ਦੀ ਲੋੜ ਹੋ ਸਕਦੀ ਹੈ ,ਤੁਹਾਨੂੰ ਮੁਫ਼ਤ ਵਿੱਚ ਤੇ ਆਪਣੀ ਭਾਸ਼ਾ ਵਿੱਚ ਜਾਣਕਾਰੀ ਅਤੇ ਮਦਦ ਪ੍ਰਾਪਤ ਕਰਨ ਦਾ ਅਧਿਕਾਰ ਹੈ ,ਕਾਲ 800-722-1471 (TTY: 800-842-5357).

فارسی (Farsi):
این اعلامیه حاوی اطلاعات مهم میباشد .این اعلامیه ممکن است حاوی اطلاعات مهم درباره فرم تقاضا و یا پوشش بیمه ای شما از طریق Premera Blue Cross باشد. به تاریخ های مهم در این اعلامیه توجه نمایید .شما ممکن است برای حفظ پوشش بیمه تان یا کمک در پرداخت هزینه های درمانی تان، به تاریخ های مشخصی برای انجام کارهای خاصی احتیاج داشته باشید .شما حق این را دارید که این اطلاعات و کمک را به زبان خود به طور رایگان دریافت نمایید. برای کسب اطلاعات با شماره 800-722-1471 (کاربران TTY تماس باشماره 800-842-5357) تماس برقرار نمایید.

Polskie (Polish):
To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Państwa wniosku lub zakresu świadczeń poprzez Premera Blue Cross. Prosimy zwrócic uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utrzymania polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie Państwo prawo do bezpłatnej informacji we własnym języku. Zadzwońcie pod 800-722-1471 (TTY: 800-842-5357).

Português (Portuguese):
Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

Română (Romanian):
Prezenta notificare conține informații importante. Această notificare poate conține informații importante privind cererea sau acoperirea asigurării dumneavoastre de sănătate prin Premera Blue Cross. Pot exista date cheie în această notificare. Este posibil să fie nevoie să acționați până la anumite termene limită pentru a vă menține acoperirea asigurării de sănătate sau asistența privitoare la costuri. Aveți dreptul de a obține gratuit aceste informații și ajutor în limba dumneavoastră. Sunați la 800-722-1471 (TTY: 800-842-5357).

Русский (Russian):
Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

Fa'asamoa (Samoan):
Atonu ua iai i lenei fa'asilasilaga ni fa'amatalaga e sili ona taua e tatau ona e malamalama i ai. O lenei fa'asilasilaga o se fesoasoani e fa'amatala atili i ai i le tulaga o le polokalame, Premera Blue Cross, ua e tau fia maua atu i ai. Fa'amolemole, ia e iloilo fa'alelei i aso fa'apitoa olo'o iai i lenei fa'asilasilaga taua. Masalo o le'a iai ni feau e tatau ona e faia ao le'i aulia le aso ua ta'ua i lenei fa'asilasilaga ina ia e iai pea ma maua fesoasoani mai ai i le polokalame a le Malo olo'o e iai i ai. Olo'o iai iate oe le aia tatau e maua atu i lenei fa'asilasilaga ma lenei fa'amatalaga i legagana e te malamalama i ai aunoa ma se togiga tupe. Vili atu i le telefoni 800-722-1471 (TTY: 800-842-5357).

Español (Spanish):
Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):
Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon. Ang paunawa na ito ay maaaring naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang petsa dito sa paunawa. Maaring mangailangan ka na magsagawa ng hakbang sa ilang mga itinakdang panahon upang mapanatili ang iyong pagsakop sa kalusugan o tulong na walang gastos. May karapatan ka na makakuha ng ganitong impormasyon at tulong sa iyong wika ng walang gastos. Tumawag sa 800-722-1471 (TTY: 800-842-5357).

ไทย (Thai):
ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้อาจมีข้อมูลที่สำคัญเกี่ยวกับการการสมัครหรือขอบเขตประกันสุขภาพของคุณผ่าน Premera Blue Cross และอาจมีกำหนดการในประกาศนี้ คุณอาจจะต้องดำเนินการภายในกำหนดระยะเวลาที่แน่นอนเพื่อจะรักษาการประกันสุขภาพของคุณหรือการช่วยเหลือที่มีค่าใช้จ่าย คุณมีสิทธิที่จะได้รับข้อมูลและความช่วยเหลือนี้ในภาษาของคุณโดยไม่มีค่าใช้จ่าย โทร 800-722-1471 (TTY: 800-842-5357)

Український (Ukrainian):
Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страхувального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дзвоніть за номером телефону 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):
Thông báo này cung cấp thông tin quan trọng. Thông báo này có thông tin quan trọng về đơn xin tham gia hoặc hợp đồng bảo hiểm của quý vị qua chương trình Premera Blue Cross. Xin xem ngày quan trọng trong thông báo này. Quý vị có thể phải thực hiện theo thông báo đúng trong thời hạn để duy trì bảo hiểm sức khỏe hoặc được trợ giúp thêm về chi phí. Quý vị có quyền được biết thông tin này và được trợ giúp bằng ngôn ngữ của mình miễn phí. Xin gọi số 800-722-1471 (TTY: 800-842-5357).