MEDICAL POLICY – 7.01.546
Spinal Cord and Dorsal Root Ganglion Stimulation

BCBSA Ref. Policy: 7.01.25

Effective Date: July 1, 2019
Last Revised: June 11, 2019
Replaces: 7.01.25

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

Select a hyperlink below to be directed to that section.

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 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.
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.

<table>
<thead>
<tr>
<th>Site of Service for Elective Surgical Procedures</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medically necessary sites of service:</strong></td>
<td>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.</td>
</tr>
<tr>
<td>• Off campus-outpatient hospital/medical center</td>
<td></td>
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<tr>
<td>• On campus-outpatient hospital/medical center</td>
<td></td>
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<tr>
<td>• Ambulatory Surgical Center</td>
<td></td>
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<tr>
<td><strong>Inpatient hospital/medical center</strong></td>
<td>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):</td>
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<tr>
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<tr>
<td>• Anesthesia Risk</td>
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<tr>
<td>• ASA classification III or higher (see definition)</td>
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<tr>
<td>• Personal history of complication of anesthesia</td>
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<tr>
<td>• Documentation of alcohol dependence or history of cocaine use</td>
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<tr>
<td>• Prolonged surgery (&gt;3 hours)</td>
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<tr>
<td>• Cardiovascular Risk</td>
<td></td>
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<tr>
<td>• Uncompensated chronic heart failure (NYHA class III or IV)</td>
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<tr>
<td>• Recent history of myocardial infarction (MI) (&lt;3 months)</td>
<td></td>
</tr>
<tr>
<td>• Poorly controlled, resistant hypertension*</td>
<td></td>
</tr>
<tr>
<td>• Recent history of cerebrovascular accident (&lt;3 months)</td>
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<tr>
<td>• Increased risk for cardiac ischemia (drug eluting stent placed &lt; 1 year or angioplasty &lt;90 days)</td>
<td></td>
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<tr>
<td>• Symptomatic cardiac arrhythmia despite medication</td>
<td></td>
</tr>
<tr>
<td>• Significant valvular heart disease</td>
<td></td>
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<tr>
<td>Site of Service for Elective Surgical Procedures</td>
<td>Medical Necessity</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>• Liver Risk</td>
<td></td>
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<tr>
<td>o Advance liver disease (MELD Score &gt; 8)**</td>
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<tr>
<td>• Pulmonary Risk</td>
<td></td>
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<tr>
<td>o Chronic obstructive pulmonary disease (COPD) (FEV1 &lt;50%)</td>
<td></td>
</tr>
<tr>
<td>o Poorly controlled asthma (FEV1 &lt;80% despite treatment)</td>
<td></td>
</tr>
<tr>
<td>o Moderate to severe obstructive sleep apnea (OSA)***</td>
<td></td>
</tr>
<tr>
<td>• Renal Risk</td>
<td></td>
</tr>
<tr>
<td>o End stage renal disease (on dialysis)</td>
<td></td>
</tr>
<tr>
<td>• Other</td>
<td></td>
</tr>
<tr>
<td>o Morbid obesity (BMI ≥ 50)</td>
<td></td>
</tr>
<tr>
<td>o Pregnancy</td>
<td></td>
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<tr>
<td>o Bleeding disorder (requiring replacement factor, blood products, or special infusion product [DDAVP**** does not meet this criteria])</td>
<td></td>
</tr>
<tr>
<td>o Anticipated need for transfusion(s)</td>
<td></td>
</tr>
</tbody>
</table>

* 3 or more drugs to control blood pressure  
*** 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.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spinal cord stimulation trial and permanent placement</td>
<td></td>
</tr>
<tr>
<td>• Standard spinal cord stimulation</td>
<td></td>
</tr>
<tr>
<td>• High-frequency spinal cord stimulation</td>
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<tr>
<td>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:</td>
<td></td>
</tr>
<tr>
<td>• 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</td>
<td></td>
</tr>
<tr>
<td>Procedure</td>
<td>Medical Necessity</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Procedure</strong></td>
<td><strong>Medical Necessity</strong></td>
</tr>
<tr>
<td><strong>AND</strong></td>
<td>• The patient has severe and chronic neuropathic pain of the trunk or limbs resulting from actual damage to peripheral nerves (such as failed lumbar back syndrome, complex regional pain syndrome, arachnoiditis, phantom limb/stump pain, or peripheral neuropathy)</td>
</tr>
<tr>
<td>AND</td>
<td>• Member has obtained clearance by a licensed psychologist, psychiatrist or other licensed mental health professional</td>
</tr>
<tr>
<td>AND</td>
<td>• No untreated drug habituation exists</td>
</tr>
<tr>
<td>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</td>
<td></td>
</tr>
<tr>
<td><strong>Replacement of spinal cord stimulators or dorsal root ganglion neurostimulators</strong></td>
<td>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 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.</td>
</tr>
<tr>
<td><strong>Replacement of a functioning standard spinal cord stimulator with a high-frequency spinal cord stimulator is considered not medically necessary.</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Dorsal root ganglion (DRG) stimulation trial and permanent placement</strong></td>
<td>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</td>
</tr>
<tr>
<td>Procedure</td>
<td>Medical Necessity</td>
</tr>
<tr>
<td>-----------</td>
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</tr>
</tbody>
</table>
|            | 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 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 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

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spinal cord stimulation in other situations</td>
<td>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: 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) 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</td>
</tr>
</tbody>
</table>
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 or dorsal root ganglion neurostimulator
  - 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 or dorsal root ganglion neurostimulator:
  - All of the above listed criteria are met
  - 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

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>63650</td>
<td>Percutaneous implantation of neurostimulator electrode array, epidural</td>
</tr>
<tr>
<td>63655</td>
<td>Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural</td>
</tr>
<tr>
<td>63661</td>
<td>Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed</td>
</tr>
<tr>
<td>63662</td>
<td>Removal of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed</td>
</tr>
<tr>
<td>63663</td>
<td>Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed</td>
</tr>
<tr>
<td>63664</td>
<td>Revision including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed</td>
</tr>
<tr>
<td>63685</td>
<td>Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling</td>
</tr>
<tr>
<td>63688</td>
<td>Revision or removal of implanted spinal neurostimulator pulse generator or receiver</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>--------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>L8679</td>
<td>Implantable neurostimulator, pulse generator, any type</td>
</tr>
<tr>
<td>L8680</td>
<td>Implantable neurostimulator electrode, each</td>
</tr>
<tr>
<td>L8681</td>
<td>Patient programmer (external) for use with implantable programmable neurostimulator pulse generator</td>
</tr>
<tr>
<td>L8682</td>
<td>Implantable neurostimulator radiofrequency receiver</td>
</tr>
<tr>
<td>L8683</td>
<td>Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver</td>
</tr>
<tr>
<td>L8685</td>
<td>Implantable neurostimulator pulse generator, single array, rechargeable, includes extension</td>
</tr>
<tr>
<td>L8686</td>
<td>Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension</td>
</tr>
<tr>
<td>L8687</td>
<td>Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension</td>
</tr>
<tr>
<td>L8688</td>
<td>Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension</td>
</tr>
<tr>
<td>L8689</td>
<td>External recharging system for battery (internal) for use with implantable neurostimulator, replacement only</td>
</tr>
</tbody>
</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

**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.

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 patient’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.

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 2016, the 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.

The incidence of adverse events related to spinal cord stimulation have been reported to occur in 30% to 40% of cases. Adverse events can either be hardware-related or biological. Hardware-related complications include lead migration or lead failure or fracture. Biological complications include infection and pain. More severe biological complications are rare, including dural puncture headache (estimated incidence, up to 0.3%) and neurological damage (estimated incidence, 0.25%).

Other neurostimulators target the dorsal root ganglion (DRG). Dorsal root ganglia consists of sensory cell bodies that transmit input from the peripheral nervous system to the central nervous system, and play a role in neuropathic pain perception. Dorsal root ganglia are located in the epidural space between spinal nerves and the spinal cord on the posterior root in a minimal amount of cerebrospinal fluid, amenable to epidural access. Two systems targeting the DRG have received approval or clearance from the FDA.

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

**Outcome Measures**

The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials group has provided recommendations for four 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. The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials 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).

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

<table>
<thead>
<tr>
<th>Domain</th>
<th>Outcome Measure</th>
<th>Description</th>
<th>Clinically Meaningful Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain intensity</td>
<td>Numeric rating scale</td>
<td>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</td>
<td>Minimally important: 10%-20% decrease</td>
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<td></td>
<td>Verbal rating scale</td>
<td></td>
<td>Moderately important: ≥30% decrease</td>
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<td></td>
<td>Visual analog scale</td>
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<td>Substantial: ≥50% decrease</td>
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<tr>
<td>Physical functioning</td>
<td>Multidimensional Pain Inventory</td>
<td>Measures interference of pain with physical functioning</td>
<td>≥0.6-point decrease</td>
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<td></td>
<td>Interference Scale</td>
<td>60 items, self-report</td>
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<td></td>
<td></td>
<td>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</td>
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<tr>
<td></td>
<td></td>
<td>Items rated on 0- to 6-point scale</td>
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<tr>
<td></td>
<td></td>
<td>Interference subscale score calculated by mean of subscale items</td>
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<tr>
<td></td>
<td>Brief Pain Inventory</td>
<td>Measures intensity, quality, relief and interference of pain and patients’ ideas of the causes of pain</td>
<td>1-point decrease</td>
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<tr>
<td></td>
<td>Interference Scale</td>
<td>7 items, self-report</td>
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<tr>
<td></td>
<td></td>
<td>Mean of the 7 interference items can be used as a measure of pain interference</td>
<td></td>
</tr>
<tr>
<td>Domain</td>
<td>Outcome Measure</td>
<td>Description</td>
<td>Clinically Meaningful Difference</td>
</tr>
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</tbody>
</table>
|                       | Oswestry Disability Index                           | 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 the greatest disability  
Total score calculated by taking the mean of the section scores and multiplying by 100 | 10 points$^9$                      |
| General                | Generic measure of physical functioning             | 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$^{10,11,12}$           |
| Emotional functioning  | Beck Depression Inventory$^{13}$                    | 21 items, self-report  
Measures severity of current symptoms of depressive disorders  
Scores range from 0 to 63 | ≥5-point decrease$^5$                  |
|                       | Profile of Mood States$^{14}$                       | 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$^5$          |
| 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 |
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 HF SCS, the evidence includes three 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 HF 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 many case series. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use,
and treatment-related morbidity. The unblinded RCT found that patients receiving DRG neurostimulation had significantly higher rates of treatment success (physical functioning score and quality of life measures), at 3 and 12 months than those receiving standard SCS devices. DRG neurostimulation was found to be noninferior to SCS in percentage achieving >50% pain reduction, emotional functioning score, and SF-36 scores. Both groups experienced paresthesias, but patients 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. While most of the case series were small (sample sizes ranged from 10 to 65), all reported results that were consistent with the RCT results. The largest case series had the longest follow-up, reporting continued improvements in pain and psychological scores through three years. The evidence is sufficient to determine that the technology results in meaningful improvement in the net health outcome.

**Critical Limb Ischemia**

For individuals who have critical limb ischemia who receive SCS, the evidence includes several small 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 one meta-analysis that included a nonrandomized study reported 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 two recent RCTs, there was no significant benefit in 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 one adverse event in two patients with the device turned on and in two 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 case series. 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**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02514590a</td>
<td>Wireless High Frequency Spinal Cord Stimulation for Chronic Pain</td>
<td>80</td>
<td>Feb 2019</td>
</tr>
<tr>
<td>NCT02902796</td>
<td>Comparison of 1000 Hertz (Hz), Burst, and Standard Spinal Cord Stimulation in Chronic Pain Relief</td>
<td>19</td>
<td>Dec 2019</td>
</tr>
<tr>
<td>NCT02093793a</td>
<td>A Randomized Controlled Study to Evaluate the Safety and Effectiveness of the Precision Spinal Cord Stimulator System Adapted for High-Rate Spinal Cord Stimulation</td>
<td>383</td>
<td>Nov 2019</td>
</tr>
<tr>
<td>NCT03014583</td>
<td>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)</td>
<td>28</td>
<td>Jul 2020</td>
</tr>
<tr>
<td>NCT No.</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
</tr>
<tr>
<td>-----------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>NCT03318172</td>
<td>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</td>
<td>100</td>
<td>Jul 2019</td>
</tr>
<tr>
<td>NCT03228420</td>
<td>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</td>
<td>360</td>
<td>Jul 2020</td>
</tr>
<tr>
<td>Unpublished</td>
<td>The Pain Suppressive Effect of Alternative Spinal Cord Stimulation Frequencies</td>
<td>30</td>
<td>Nov 2016 (unknown)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

* Denotes industry-sponsored or cosponsored trial.

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**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. The Association issued recommendations on spinal cord stimulation (SCS), considered weak due to the amount and consistency of the evidence. The recommendations supported the use of SCS for failed back surgery syndrome and for complex regional pain syndrome (Table 3). In regards to high frequency stimulation and dorsal root ganglion stimulation, the publication states that long-term effectiveness of these techniques needs to be determined with further studies.
Table 3. International Association for the Study of Pain
Recommendations for SCS

<table>
<thead>
<tr>
<th>Indication</th>
<th>Comments</th>
<th>Quality of Evidence</th>
<th>Strength of Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRPS 1</td>
<td>Long-term benefits demonstrated, though benefits may diminish over time (in RCT, reoperation rate was 42%). May be considered for patients not responding to non-invasive treatments and sympathetic nerve blocks or for whom nerve blocks would be inappropriate.</td>
<td>Moderate</td>
<td>Weak</td>
</tr>
<tr>
<td>CRPS 2</td>
<td>Limited evidence</td>
<td>Low</td>
<td>Inconclusive</td>
</tr>
<tr>
<td>FBSS with radiculopathy</td>
<td>Based on 2 RCTs, appears to be better than reoperation and conventional medical management, However, response rates were relatively low and complication rates were relatively high.</td>
<td>Moderate</td>
<td>Weak</td>
</tr>
</tbody>
</table>

CRPS: complex regional pain syndrome; FBSS: failed back surgery syndrome; SCS: spinal cord stimulation; RCT: randomized controlled trial.

**American Society of Interventional Pain Physicians**

The American Society of Interventional Pain Physicians (2013) updated its evidence-based guidelines for interventional techniques for the management of chronic spinal pain. 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 FBSS, after exhausting multiple conservative and interventional modalities”.

Earlier evidence-based guidelines from the Society (2007) 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. Reported complications with SCS ranged from infection, hematoma, nerve damage, lack of appropriate paresthesia coverage, paralysis, nerve injury, to death.
American Society of Anesthesiologists

The American Society of Anesthesiologists' Task Force and the American Society of Regional Anesthesia and Pain Management (2011) updated and published guidelines for chronic pain management. The guideline concluded that SCS "may be used in the multimodal treatment of persistent radicular pain in patients who have not responded to other therapies" and that SCS "may also be considered for other selected patients (eg, CRPS, peripheral neuropathic pain, peripheral vascular disease, and postherpetic neuralgia.)"

International Neuromodulation Society

The International Neuromodulation Society convened a Neuromodulation Appropriateness Consensus Committee (NACC) to develop best practices for the use of dorsal root ganglion (DRG) stimulation for the treatment of chronic pain syndromes. The NACC was comprised of experts in anesthesiology, neurosurgery, and pain medicine. The NACC performed a systematic literature search through June 2017 and identified 29 publications providing evidence for the consensus recommendations. The evidence was graded using the modified Pain Physician criteria and the U.S. Preventive Services Task Force criteria. Table 4 summarizes the consensus recommendations on the use of DRG stimulation. Additional recommendations on the DRG stimulation procedure are provided in the publication.

Table 4. NACC Consensus Recommendations for the Use of DRG Stimulation

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Level</th>
<th>Grade</th>
<th>Consensus</th>
</tr>
</thead>
<tbody>
<tr>
<td>DRG stimulation should be considered primarily for patients with focal neuropathic pain syndromes with identified pathology</td>
<td>I</td>
<td>A</td>
<td>Strong</td>
</tr>
<tr>
<td>DRG stimulation is recommended for CRPS type I or type II of the lower extremity</td>
<td>I</td>
<td>A</td>
<td>Strong</td>
</tr>
<tr>
<td>DRG stimulation for CRPS type I or type II of the upper extremity requires more study</td>
<td>II-2</td>
<td>A</td>
<td>Strong</td>
</tr>
<tr>
<td>DRG stimulation for DPN may be effective based on limited data. Since there is good evidence for SCS, the use of DRG must be justified.</td>
<td>III</td>
<td>C</td>
<td>Strong</td>
</tr>
<tr>
<td>Evidence for DRG stimulation for non-diabetic peripheral neuropathy is limited; use should be determined on a case-by-case basis.</td>
<td>III</td>
<td>B</td>
<td>Moderate</td>
</tr>
</tbody>
</table>
Evidence for DRG stimulation for chronic postoperative surgical pain is limited; use should be determined on a case-by-case basis. III C Moderate

DRG stimulation for pelvic pain should be used under strict criteria depending on mechanism of injury and visceral/somatic designation. Psychologic comorbidity is a contraindication. III I Moderate

DRG stimulation for groin pain is recommended. II-2 B Strong

DRG stimulation is superior to standard SCS for unilateral focal pain from CRPS type I or type II of the lower extremity I A Strong

No evidence for DRG stimulation over SCS for other indications

CRPS: complex regional pain syndrome; DPN: diabetic peripheral neuropathy; DRG: dorsal root ganglion; NACC: Neuromodulation Appropriateness Consensus Committee; SCS: spinal cord stimulation.

**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. 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.

In the same guidance, the National Institute for Health and Care Excellence 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, 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.79

Regulatory Status

A large number of neurostimulator devices, some used for 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 the 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.”15 This device uses a higher frequency of electrical stimulation (10 kHz) than standard devices.

In February 2016, the Axium Neurostimulator System (Abbot) was approved by the FDA through the premarket approval process. This implanted device stimulates the DRG. 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 the 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, the FDA approved BurstDR™ stimulation (St. Jude Medical), a clinician programmer application that provides intermittent “burst” stimulation for patients with certain St. Jude SCS devices.

In August 2017, the PrecisionTM Spinal Cord Stimulator (Boston Scientific) was approved by the FDA through the premarket approval process.

**References**


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
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<tbody>
<tr>
<td>04/10/12</td>
<td>New policy replacing 7.01.25.</td>
</tr>
<tr>
<td>07/20/12</td>
<td>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.</td>
</tr>
<tr>
<td>08/27/12</td>
<td>Update Related Policies – Add 7.01.20. Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
</tr>
<tr>
<td>04/16/13</td>
<td>Replace policy. No change to policy statements. References 14, 18, 21, 22 added.</td>
</tr>
<tr>
<td>12/19/13</td>
<td>Update Related Policies. Remove 1.01.19 as it was archived.</td>
</tr>
<tr>
<td>07/14/14</td>
<td>Annual Review. Policy statement revised. Spinal cord stimulation may now be considered medically necessary for pain due to complex regional pain syndrome when</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>03/31/15</td>
<td>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.</td>
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<tr>
<td>05/27/15</td>
<td>Coding update; ICD-9 procedure code 86.96 added to policy; ICD-10 PCS codes adding per cross walk remediation.</td>
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<tr>
<td>01/29/16</td>
<td>Coding update. Added HCPCS code L8679.</td>
</tr>
<tr>
<td>05/01/16</td>
<td>Annual Review, approved April 12, 2016. Clarified policy statement adding, licensed mental health provider. No new references added.</td>
</tr>
<tr>
<td>03/01/17</td>
<td>Coding Update. Removed CPT code 95973 as it was deleted as of 01/01/2016.</td>
</tr>
<tr>
<td>04/14/17</td>
<td>Policy moved into new format; no change to policy statements. Evidence Review section reformatted.</td>
</tr>
<tr>
<td>07/01/17</td>
<td>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.</td>
</tr>
<tr>
<td>08/25/17</td>
<td>Coding update, removed CPT codes 95970, 95971, and 95972.</td>
</tr>
<tr>
<td>10/01/17</td>
<td>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.</td>
</tr>
<tr>
<td>02/01/18</td>
<td>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.</td>
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<tr>
<td>02/06/18</td>
<td>Coding update, removed HCPCS code C1822.</td>
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<tr>
<td>02/13/18</td>
<td>Minor update; updated Introduction section.</td>
</tr>
<tr>
<td>03/01/18</td>
<td>Note added that this policy has been revised. Added link to revised policy that will become effective June 1, 2018.</td>
</tr>
<tr>
<td>06/01/18</td>
<td>Minor update; removed note and link to updated policy. Surgery Site of Service criteria becomes effective.</td>
</tr>
<tr>
<td>07/01/18</td>
<td>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</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
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<tr>
<td>unchanged. Related Information section revised to add burst neurostimulation as an alternate programming of a standard SCS device.</td>
<td></td>
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<tr>
<td>05/01/19</td>
<td>Minor update, clarified Site of Service requirements.</td>
</tr>
<tr>
<td>07/01/19</td>
<td>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.</td>
</tr>
</tbody>
</table>

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200 Independence Avenue SW, Room 509F, HHH Building
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Română (Romanian):

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).

Español (Spanish):
Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud de 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).

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 ймовірність 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. Дзвініть за номером телефону 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):