Spinal Cord and Dorsal Root Ganglion Stimulation

Description of Procedure or Service

Spinal cord stimulation (SCS) delivers low voltage electrical stimulation to the dorsal columns of the spinal cord to block the sensation of pain. Spinal cord stimulation devices have a radiofrequency receiver that is surgically implanted and a power source (battery) that is either implanted or worn externally. Other neurostimulators target the dorsal root ganglion.

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 to blockage of facilitative circuits. 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 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 four to eight electrodes, with eight electrodes more commonly used for complex pain patterns. There are two basic types of power source. In one type the power source (battery) can be surgically implanted or worn externally with an antenna over the receiver. In 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 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 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 on the order 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...
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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. 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 FDA.

Regulatory Status
A large number of neurostimulator devices, some used for spinal cord stimulation, have received U.S. Food and Drug Administration (FDA) premarket approval (PMA). The Cordis programmable neurostimulator from Cordis, Corp. was approved in 1981, the Itrel® manufactured by Medtronic was approved in 1984 and the Genesis and Eon devices from St. Jude Medical were approved in 2001. In April 2004, Advanced Bionics received PMA for its Precision Spinal Cord Stimulator as an aid in management of chronic, intractable trunk and limb pain. All are fully implanted devices.

In May 2015, the Nevro Senza™ Spinal Cord Stimulator (Nevro Corp., Menlo Park, CA), 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.” This device uses a higher frequency of electrical stimulation (10 kHz) than standard devices.

In February 2016, the Axium Neurostimulator System (Abbott) was approved by FDA through the PMA process. The implanted device stimulates the dorsal root ganglion. 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 November 2016, the original PMA was amended to include the Proclaim Dorsal Root Ganglion (DRG) Neurostimulation System.

In August 2016, the Freedom Spinal Cord Stimulator (Stimwave Technologies, Fort Lauderdale, FL) was cleared for marketing by FDA through the 510(k) process. It is a wireless injectable stimulator 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 (i.e., levels T7 to L5) or to target the dorsal root ganglion.

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

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

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.

Policy

BCBSNC will provide coverage for Spinal Cord and Dorsal Root Ganglion Stimulation when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.
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Benefits Application
This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Spinal Cord and Dorsal Root Ganglion Stimulation is covered
A. A trial treatment with standard or high-frequency spinal cord stimulation or dorsal root ganglion stimulation using a temporary stimulator in the epidural space may be considered medically necessary when all of the following criteria are met:
   1. The patient has severe and chronic neuropathic pain of the trunk or limbs resulting from actual damage to peripheral nerves; and
   2. Other pain management modalities (pharmacologic, surgical, psychological, and physical therapies) have been tried and failed, or judged to be unsuitable or contraindicated; and
   3. The patient has undergone careful screening, evaluation and diagnosis by a multidisciplinary pain management team (including psychological as well as physical evaluation); and
   4. No untreated drug habituation exists.
B. Placement of a permanent spinal cord stimulator or dorsal root ganglion stimulator may be considered medically necessary and eligible for coverage when the above medical necessity criteria for a trial treatment of spinal cord stimulation or dorsal root ganglion stimulation are met, the trial is performed, and the patient has demonstrated pain relief of at least 50% for a minimum of 48 hours with the temporarily implanted electrode as documented in the medical record.

When Spinal Cord and Dorsal Root Ganglion Stimulation is not covered
A. Spinal cord stimulation or dorsal root ganglion stimulation for neuropathic pain of the trunk or limbs, resulting from damage to the peripheral nerves, is considered not medically necessary when the above criteria are not met.
B. Spinal cord stimulation or dorsal root ganglion stimulation is considered investigational for all other indications including but not limited to the following:
   1. treatment of critical limb ischemia as a technique to forestall amputation
   2. treatment of refractory angina pectoris
   3. treatment of nociceptive pain (pain resulting from irritation rather than damage to the nerves)
   4. treatment of visceral pain
   5. treatment of cancer-related pain
   6. treatment of central deafferentation pain (pain related to central nervous system damage from stroke or spinal cord surgery).
   7. treatment of heart failure

Policy Guidelines
Nociceptive pain arises from stimulation of pain receptors within tissue that has been damaged or involved in an inflammatory process.

Neuropathic pain results from damage to or dysfunction of the peripheral or central nervous system, rather than stimulation of pain receptors. Diagnosis is suggested by pain out of

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proportion to tissue injury, dysesthesia (e.g., burning, tingling), and signs of nerve injury detected during neurologic examination.

Common indications for spinal cord stimulation include, but are not limited to, failed back syndrome, complex regional pain syndrome (i.e., reflex sympathetic dystrophy), arachnoiditis, radiculopathies, phantom limb/stump pain, and peripheral neuropathy. Spinal cord stimulation is generally not effective in treating nociceptive pain and central deafferentation pain.

“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.

For individuals who have treatment-refractory chronic pain of the trunk or limbs who receive standard SCS, the evidence includes systematic reviews and randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Available RCTs are heterogeneous regarding underlying diagnoses in the selected patient populations. However, those that have included 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 very limited options. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have treatment-refractory chronic pain of the trunk or limbs who receive high-frequency SCS, the evidence includes a systematic review and three RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. One RCT comparing high-frequency to 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 to other trials of SCS due to the different patient populations, short treatment periods, and the crossover period effect. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have treatment-refractory chronic pain of the trunk or limbs who receive dorsal root ganglion neurostimulation, the evidence includes systematic reviews, one 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 dorsal root ganglion 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 36-Item Short-Form Health Survey 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. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

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

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 RCT (N=66) comparing spinal cord stimulation using active stimulation with sham-control in patients who had New York Heart Association functional class III heart failure and a left ventricular ejection fraction of 35% or less did not find significant differences between groups, but might have been underpowered to do so. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 63650, 63655, 63661, 63662, 63663, 63664, 63685, 63688, 95970, 95971, 95972, 95973, C1820, C1822, L8679, L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688, L8689.

Medical documentation must include:

- All other treatment modalities used, including pharmacologic agents, surgeries, physical, or psychological, transcutaneous and percutaneous electrical nerve stimulation, if appropriate) and the results of these treatments
- Supporting documentation of the screening, evaluation, and diagnosis by a multidisciplinary team
- Evidence that all the facilities, equipment, professional and support personnel required for the proper diagnosis, treatment and follow-up of the patient are available.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources


Plan Consultant - 8/95

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Senior Medical Director Review - 2/2009
Medical Director - 8/2010
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Specialty Matched Consultant Advisory Panel – 10/2018

Policy Implementation/Update Information

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
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<tbody>
<tr>
<td>3/80</td>
<td>Original policy: Generally accepted medical practice for treating chronic intractable pain</td>
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<tr>
<td>6/83</td>
<td>Reaffirmed</td>
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<tr>
<td>6/84</td>
<td>Reaffirmed</td>
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<tr>
<td>12/85</td>
<td>Revised: Investigational for treating motor function disorders</td>
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<tr>
<td>8/88</td>
<td>Reviewed: Eligible for coverage for severe, chronic pain. Investigational for all other neurological diseases.</td>
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<tr>
<td>7/96</td>
<td>Reaffirmed: National Association reviewed 3/96. No changes. Combined Local and National by adding list of codes from Local policy.</td>
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<tr>
<td>12/99</td>
<td>Medical Policy Advisory Group</td>
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<tr>
<td>6/01</td>
<td>63690, 63691 deleted from coding section. 95970-95973 added to coding section.</td>
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</table>
| 8/02 | Specialty Matched Consultant Advisory Panel review 7/12/2002. Revised statement under the "when it is not covered" section for clarity. Changed title from Spinal Cord and Deep Brain Stimulation. Billing/Coding section revised. CPT codes 61855 and
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61865 deleted and replaced with 61862. HCPCS codes E0751 and E0753 deleted and added E0752 and E0754. Reference added to Scientific References.


1/6/05 Deleted HCPCS code E0752 from "Billing/Coding" section.


1/17/07 Added HCPCS codes L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688 and L8689 to "Billing/Coding" section.

7/14/08 Specialty Matched Consultant Advisory Panel review 5/29/08. Added the statement; "The most recent studied indication is for patients with refractory chest pain who are not candidates for surgical revascularization." to "Description" section. Changed the first sentence under the "When Covered" section from "For the treatment of" to "A trial treatment of spinal cord stimulation using a temporary stimulator may be considered medically necessary for severe and chronic neuropathic pain when all of the following criteria are met." The last paragraph in the "When Covered" section was clarified to indicate; "It is anticipated that if the patient demonstrates pain relief of at least 50% for one week with a temporarily implanted electrode a permanent spinal cord stimulator will be implanted. References added.

3/16/09 Medical policy reviewed by Senior Medical Director 2/6/09. Reformatted the "When Covered" section for ease of administration. Changed wording in "B. Placement of a permanent spinal cord stimulator may be considered medically necessary and eligible for coverage when the above medical necessity criteria for a trial treatment of spinal cord stimulation are met, the trial is performed, and the patient has demonstrated pain relief of at least 50% for one week at least 48 hours with the temporarily implanted electrode as documented in the medical record." Reformatted the "When Not Covered" section and added additional indications determined to be investigational as follows: "treatment of refractory angina, treatment of nociceptive pain (pain resulting from irritation rather than damage to the nerves), treatment of visceral pain, and treatment of central deafferentation pain (pain related to central nervous system damage from stroke or spinal cord surgery)." No change in policy statement or intent of policy. "Policy Guidelines" added. References added. (btw)

1/5/10 Added new CPT codes: 63661, 63662, 63663, and 63664 to "Billing/Coding" section. Removed deleted CPT code 63660. (btw)

6/22/10 Policy Number(s) removed (amw)

8/31/10 Medical Director review 8/5/2010. "Description" section revised. Added to the “When Covered” section, 1. “that has been refractory to all other pain therapies.” and “5. No untreated drug habituation exists”. Removed the following criteria statements; “Treatment is consistent with the multidisciplinary evaluation findings and management recommendations; and The patient is capable and willing to comply with the treatment plan.”
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Changed statement in “B” from “the patient has demonstrated pain relief of at least 50% for at least 48 hours” to “the patient has demonstrated pain relief of at least 50% for a minimum of 48 hours with the temporarily implanted electrode with the temporarily implanted electrode No change to policy intent. References added. (btw)

12/21/10 Specialty Matched Consultant Advisory Panel review 11/29/2010. No change to policy. (btw)

3/29/11 References updated. (btw)

1/10/12 Specialty Matched Consultant Advisory Panel review 11/30/11. “Description” section revised. No change to policy statement. (btw)

3/30/12 Reference added. (btw)

11/13/12 Specialty Matched Consultant Advisory Panel review 10/17/2012. Added “in the epidural space” to A. in the When Covered section for clarification. No change to policy intent. (btw)

2/26/13 Reference added. (btw)

11/12/13 Specialty Matched Consultant Advisory Panel review 10/16/2013. No change to policy. (btw)

12/31/13 Added new 2014 HCPCS code, L8679, to Billing/Coding section. (btw)

2/25/14 “treatment of cancer-related pain” added to the When Not Covered statement. Policy Guidelines updated. No change to policy intent. (btw)

12/9/14 Specialty Matched Consultant Advisory Panel review 10/28/2014. Medical Director review. No change to policy statement. (sk)

3/31/15 Reference added. Treatment of heart failure added to investigational statement. (sk)


12/30/15 Code C1822 added to Billing/Coding section. (sk)


6/30/17 Reference added. Description section and Policy Guidelines section updated. Wireless injectable dorsal root ganglion neurostimulation added to When Not Covered section. High frequency spinal cord stimulation added to When Covered section. (sk)


6/8/18 Reference added. Policy Guidelines updated. Policy Guidelines section revised to add Burst neurostimulation as an alternate programming of a standard SCS device. (sk)

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11/26/19  Specialty Matched Consultant Advisory Panel review 10/16/2019. (sk)

8/25/20  Reference added. (sk)


10/19/21  Reference added. Policy Guidelines updated. Policy statement updated to add Dorsal Root Ganglion Stimulation trial to criteria for permanent coverage. Dorsal Root Ganglion Stimulation added to item B. in When Not Covered section. Policy noticed 10/19/2021 for effective date 1/1/2022. (sk)


Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.