Spinal Cord Stimulation “Notification”

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.

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 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. In one type the power source (battery) can be surgically implanted. In the other a radiofrequency receiver is implanted, and the power source is worn externally with an antenna over the receiver. 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 radioreceiver/transducer are permanently implanted. Successful spinal cord stimulation may require extensive programming of the neurostimulators to identify the optimal electrode combinations and stimulation channels. Computer-controlled programs are often used to assist the physician in studying the millions of programming options when complex systems are used.

Traditional SCS devices use electrical stimulation with a frequency on the order of 100 to 1000 Hz. Some devices allow adjustment of the frequency settings. At least 1 newer device is available that uses higher frequency stimulation (10,000 Hz). The high-frequency stimulation is proposed to be associated with fewer paresthesias, which are a recognized effect of SCS.

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 and the Itrel® manufactured by Medtronic was approved in 1984. In April 2004, Advanced Bionics received...
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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, FDA approved the Nevro Senza™ Spinal Cord Stimulator (Nevro Corp., Menlo Park, CA), a totally implantable neurostimulator device, 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, intractable low back pain, and leg pain.” This device uses a higher frequency of electrical stimulation (10 kHz) than standard devices.

***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 Stimulation when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

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 Stimulation is covered

A. A trial treatment of non-high-frequency spinal cord 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 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 a minimum of 48 hours with the temporarily implanted electrode as documented in the medical record.

When Spinal Cord Stimulation is not covered

A. High-frequency spinal cord stimulation is investigational for the treatment of severe and chronic pain of the trunk or limbs.

B. Spinal cord 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.

C. Spinal cord stimulation is considered investigational for all other indications including but not limited to the following:
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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 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.

The evidence for standard SCS in individuals who have treatment-refractory chronic pain of the trunk or limb 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 mixed in terms of the 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 qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for high-frequency SCS in individuals who have treatment-refractory chronic pain of the trunk or limbs includes 2 RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. One RCT comparing high-frequency to standard stimulation found a large and statistically significant benefit associated with high-frequency SCS. In contrast, a smaller study found no benefit for those receiving high-frequency stimulation compared with sham control. Given the uncertainty in these findings, additional trials are needed to corroborate the benefit of high-frequency stimulation. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for SCS in individuals who have critical limb ischemia or refractory angina pectoris or heart failure includes RCTs. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. Available RCTs have not consistently demonstrated a benefit associated with SCS treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for SCS in individuals who have cancer-related pain 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.
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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.


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


Policy Implementation/Update Information

3/80 Original policy: Generally accepted medical practice for treating chronic intractable pain
6/83 Reaffirmed
6/84 Reaffirmed
12/85 Revised: Investigational for treating motor function disorders
8/88 Reviewed: Eligible for coverage for severe, chronic pain. Investigational for all other neurological diseases.
7/96 Reaffirmed: National Association reviewed 3/96. No changes. Combined Local and National by adding list of codes from Local policy.
12/99 Medical Policy Advisory Group
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6/01 63690, 63691 deleted from coding section. 95970-95973 added to coding section.


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 5/29/2008. 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 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
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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.” 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)

5/31/16 Reference added. Description Section updated. Policy Guidelines updated. Added “high frequency spinal cord stimulation is investigational for the treatment of severe and chronic pain the trunk or limbs” to the When Not Covered. Section. Policy noticed 5/31/2016 for effective date to be determined. (sk)
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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.