

MEDICAL POLICY



POLICY TITLE	SPINAL CORD STIMULATION
POLICY NUMBER	MP-1.069

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I. POLICY

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Spinal cord stimulation may be 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 the following criteria are met.

- The treatment is used only as a last resort; other treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) have been tried and failed or are judged to be unsuitable or contraindicated;
- Pain is neuropathic in nature; i.e., resulting from actual damage to the peripheral nerves. Common indications include, but are not limited to, failed back syndrome, complex regional pain syndrome (i.e., reflex sympathetic dystrophy), arachnoiditis, radiculopathies, phantom limb/stump pain, peripheral neuropathy. Spinal cord stimulation is generally not effective in treating nociceptive pain (resulting from irritation, not damage to the nerves) and central deafferentation pain (related to central nervous system damage from a stroke or spinal cord injury).
- No serious untreated drug habituation exists;
- Demonstration of at least 50% pain relief with a temporarily implanted electrode precedes permanent implantation;
- All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment, and follow-up of the patient are available.

Spinal cord stimulation is considered **investigational** for all other indications, including but not limited to treatment of critical limb ischemia as a technique to forestall amputation and as a treatment for refractory angina pectoris. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

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Cross-Reference

MP-1.042 Deep Brain Stimulation
MP-6.048 Electrical Stimulation for the Treatment of Arthritis
MP-6051 Functional Electrical Stimulation
MP-6.049 H-Wave Electrical Stimulation
MP-6.047 Interferential Stimulation for the Treatment of Pain
MP-6.050 Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neurostimulation Therapy
MP-6045 Sympathetic Therapy for the Treatment of Pain
MP-6.046 Threshold Electrical Stimulation as a Treatment of Motor Disorders
MP 6.020 Transcutaneous Electrical Nerve Stimulation (TENS)

II. PRODUCT VARIATIONS

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[N] = No product variation, policy applies as stated

[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids

[N] Indemnity

[N] PPO

[N] SpecialCare

[N] HMO

[N] POS

Y] SeniorBlue HMO*

[Y] FEP PPO**

[Y] SeniorBlue PPO*

* Refer to Centers for Medicare and Medicaid (CMS) National Coverage Determination (NCD) 160-7. Electrical Nerve Stimulators and Novitas Solutions Local Coverage Determination (LCD) L34705 Spinal Cord Stimulation (Dorsal Column Stimulation).

** Refer to FEP Medical Policy Manual MP-7.01.25 Spinal Cord Stimulation. The FEP Medical Policy manual can be found at:<http://bluewebportal.bcbs.com/landingpagelevel3/504100?docId=23980>

III. DESCRIPTION/BACKGROUND

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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.

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Spinal cord stimulation (SCS) devices consist of several components: 1) the lead that delivers the electrical stimulation to the spinal cord; 2) an extension wire that conducts the electrical stimulation from the power source to the lead; and 3) a power source that generates the electrical stimulation. The lead may incorporate from 4 to 8 electrodes, with 8 electrodes more commonly used for complex pain patterns, such as bilateral pain or pain extending from the limbs to the trunk. There are two basic types of power source. 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.

Spinal cord stimulation 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 (CRPS) (i.e., chronic reflex sympathetic dystrophy). There has also been interest in spinal cord stimulation as a treatment of critical limb ischemia, primarily in patients who are poor candidates for revascularization and in patients with refractory chest pain. The neurophysiology of pain relief after spinal cord stimulation is uncertain but may be related to either activation of an inhibitory system or blockage of facilitative circuits.

The patient's pain distribution pattern dictates at what level in the spinal cord the stimulation lead is placed. The pain pattern may influence the type of device used; for example, a lead with 8 electrodes may be selected for those with complex pain patterns or bilateral pain. Implantation of the spinal cord stimulator is typically a 2-step process. Initially, the electrode is temporarily implanted in the epidural space, allowing a trial period of stimulation. Once treatment effectiveness is confirmed (defined as at least 50% reduction in pain), the electrodes and radio-receiver/transducer are permanently implanted. Successful spinal cord stimulation may require extensive programming of the neurostimulators to identify the optimal electrode combinations and stimulation channels. Computer-controlled programs are often used to assist the physician in studying the millions of programming options when complex systems are used.

Regulatory Status

A number of total implanted spinal cord stimulators 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(R) manufactured by Medtronic was approved in 1984. 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.

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IV. RATIONALE

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The most recent literature search for this policy was performed for the period November 2011 through November 2012. Following is a summary of the key literature to date:

Chronic trunk or limb pain

In 2009, a systematic review of randomized controlled trials (RCTs) and observational studies of spinal cord stimulation (SCS) in post-lumbar surgery syndrome was undertaken by Frey and colleagues. (1) Primary outcome measures were short term (≤ 1 year) and long-term (>1 year) pain relief, and secondary measures were improvement in functional status, psychological status, return to work, and reduction in opioid intake. The authors caution that the paucity and heterogeneity of the literature are limitations of the review. Using U.S Preventive Services Task Force quality ratings, the authors found Level II-1 evidence (from well-designed controlled trials without randomization) or II-2 evidence (from well-designed cohort or case-control analytic studies, preferably from more than one center or research group) for clinical use of the treatment on a long term-basis.

Also in 2009, Simpson and colleagues performed a systematic review of the literature to obtain clinical and cost-effectiveness data for SCS in adults with chronic neuropathic or ischemic pain with inadequate response to medical or surgical treatment other than SCS. (2) Trials for failed back surgery syndrome and complex regional pain syndrome type I suggested that SCS was more effective than conventional medical management (CMM) or reoperation in reducing pain. The authors concluded “evidence from CLI [critical limb ischaemia] trials suggests that SCS was more effective than CMM in reducing the use of analgesics up to 6 months, but not at 18 months. Although there was significant pain relief achieved, there was no significant difference between groups in terms of pain relief, for SCS versus CMM or analgesics treatment. SCS had similar limb survival rates to CMM, or analgesics treatment, or prostaglandin E1. SCS and CMM were similarly effective in improving HRQoL (*health-related quality of life*).”

Representative RCTs on spinal cord stimulation for treating pain are described below:

A multicenter randomized trial published in 2007 by Kumar and colleagues (the PROCESS study) compared SCS (plus conventional medical management) with medical management alone in 100 patients with failed back surgery syndrome. (3) Leg pain relief ($>50\%$) at 6 months was observed in 24 (48%) SCS-treated patients and in 4 (9%) controls, with an average leg pain visual analogue scale (VAS) score of 40 in the SCS group and 67 in the conventional management control group. Between 6 and 12 months, 5 (10%) patients in the SCS group and 32 (73%) patients in the control group crossed over to the other condition. Of the 84 patients who were implanted with a stimulator over the 12 months of the study, 27 (32%) experienced device-related complications.

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In 2008, Kemler and colleagues reported 5-year outcomes from a randomized trial of 54 patients with complex regional pain syndrome (CRPS) (4). Twenty-four of the 36 patients assigned to SCS and physical therapy were implanted with a permanent stimulator after successful test stimulation; 18 patients were assigned to physical therapy alone. Five-year follow-up showed a 2.5-cm change in VAS pain score in the SCS group (n=20) and a 1.0-cm change for the control group (n=13). Pain relief at 5 years was not significantly different between the groups; 19 (95%) patients reported that for the same result, they would undergo the treatment again. Ten (42%) patients underwent reoperation due to complications.

Conclusions: The evidence on SCS for treatment of chronic limb or trunk pain consists of a number of small RCTs that include patients with refractory pain due to conditions such as failed back surgery and complex regional pain syndrome. These studies are heterogeneous in terms of patient populations and outcomes, but generally report an improvement in pain and a reduction in requirement for medications. Because these patients have few other options, this evidence suggests that SCS is a reasonable treatment option.

Critical limb ischemia

Critical limb ischemia is described as pain at rest or the presence of ischemic limb lesions. If the patient is not a suitable candidate for limb revascularization (typically due to insufficient distal runoff), it is estimated that amputation will be required in 60–80% of these patients within 1 year. SCS has been investigated in this small subset of patients as a technique to relieve pain and decrease the incidence of amputation.

A systematic review from the Cochrane group on the use of SCS in peripheral vascular diseases was updated in 2005. (5) Included were 6 European studies of generally good quality with a total of 444 patients. None of the studies were blinded. At 12 months' follow-up, limb salvage improved by 11% compared with any form of conservative treatment with a number needed to treat (NNT) of 9. The SCS patients required significantly fewer analgesics, and more patients reached Fontaine stage II than in the conservative group. There was no difference in ulcer healing. The overall risk of complications or additional SCS treatment was 17%, with a number needed to harm (NNH) of 6. The report concludes that there is evidence to favor SCS over standard conservative treatment to improve salvage and clinical situation in patients with critical leg ischemia but that “the benefits of SCS against the possible harm of relatively mild complications and costs must be considered.” Analysis of data and cost calculations from a randomized trial with 120 patients previously published in 1999 by Klomp and colleagues (6) showed that the difference in amputation rate at 12 months when SCS was provided in addition to best medical care was no longer present at 24 months, and there was no difference in survival rate at 24 months. (7)

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In 2009, Klomp and colleagues published a meta-analysis of 5 randomized trials on spinal cord stimulation for prevention of amputations in patients with critical limb ischemia. (8) They found insufficient evidence that SCS is more efficacious than best medical treatment alone. They also conducted additional analyses of data from their 1999 RCT to identify factors associated with a better or worse prognosis. They found that patients with ischemic skin lesions had a higher risk of amputation compared to patients with other risk factors. There were no significant interactions between this or any other prognostic factor. The analyses did not identify any subgroup of patients who might benefit from SCS.

Conclusions: A number of small RCTs of SCS versus usual care have been completed on patients with critical limb ischemia. These studies report that SCS reduces pain, but the impact on limb amputations is less certain. Some studies have shown a small improvement in amputation rates, but others have not. This evidence is not sufficient to determine whether SCS improves outcomes for patients with critical limb ischemia.

Refractory angina pectoris

Spinal cord stimulation has been used for treatment of refractory angina in Europe for 20 years, and much of the literature on SCS comes from European centers. Several systematic reviews have been published. In 2009, Taylor et al. included 7 RCTs in a systematic review of SCS in the treatment of refractory angina. (9) The authors noted that trials were small and varied considerably in quality. They concluded that “compared to a ‘no stimulation’ control, there was some evidence of improvement in all outcomes following SCS implantation with significant gains observed in pooled exercise capacity and health related quality of life”; however, “further high quality RCT and cost effectiveness evidence is needed before SCS can be accepted as a routine treatment for refractory angina.”

In 2008, a systematic review of the literature based on the Swedish Council on Technology Assessment in Health Care report on spinal cord stimulation in severe angina pectoris was published. (10) Seven controlled studies (5 of them randomized), 2 follow-up reports, and a preliminary report, as well as 2 non-randomized studies determined to be of medium-to-high quality were included in the review. The largest RCT included 104 subjects and compared SCS and coronary artery bypass graft (CABG) in patients accepted for CABG and who were considered to have only symptomatic indication (i.e., no prognostic benefit) for CABG, according to the American College of Cardiology/American Heart Association guidelines, to run an increased risk of surgical complications, and to be unsuitable for percutaneous transluminal coronary angioplasty. Between-group differences on nitrate consumption, anginal attack frequency, and self-estimated treatment effect were not statistically significant at the 6-month follow-up. (11) At the 5-year follow-up, significantly fewer patients in the CABG group were taking long-acting nitrates, and between-group differences on quality of life and mortality were not significant. (12) Other studies included in the Swedish systematic review include one

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by McNab and colleagues from 2006, which compared SCS and percutaneous myocardial laser revascularization (PMR) in a study with 68 subjects. (13) (Note: PMR is currently considered investigational through Medical Policy Reference Manual review.) Thirty subjects in each group completed a 12-month follow-up, and differences on mean total exercise time and mean time to angina were not significant. Eleven in the SCS group and 10 in the PMR group had no angina during exercise. The remaining RCTs included in the systematic review included 25 or fewer subjects.

Several RCTs were published after the systematic review but had limitations, such as small sample size and short follow-up. In 2012, Zipes and colleagues published an industry-sponsored, single-blind, multicenter trial with sites in the United States and Canada. (14) This study, however, was terminated early. The Data and Safety Monitoring Board recommended that the study be terminated for futility after the interim analysis. A total of 118 patients with severe angina despite maximal medical treatment were enrolled in the study. Of these, 71 patients (60%) underwent SCS implantation with the Intrel III neurostimulator (Medtronic). The remaining 47 patients were found not to meet eligibility criteria post-enrollment or there were other issues e.g., withdrawal of consent. The investigators had originally been planning to randomize up to 310 patients, but enrollment was slow. Implantation was successful in 68 patients; this group was randomized to high-stimulation (n=32) or a low-stimulation control (n=36). The low-stimulation control was designed so that patients would feel paresthesia, but the effect of stimulation would be sub-therapeutic. The primary outcome was a composite variable of major adverse cardiac events (MACE), which included death from any cause, acute myocardial infarction (MI), or revascularization through 6 months. Fifty-eight of 68 patients (85%) contributed data to the 6-month analysis; analysis was by intention-to-treat. The proportion of patients experiencing MACE at 6 months did not differ significantly between groups (12.6% in the high-stimulation group and 14.6% in the low-stimulation group; p=0.81). The sample size of this study was small, and it may have been underpowered for clinically meaningful differences.

A small 2011 RCT from Italy randomly assigned 25 patients to 1 of 3 treatment groups: SCS with standard levels of stimulation (n=10), SCS with low-level stimulation (75% to 80% of the sensory threshold) (n=7), or very low-intensity SCS (n=8). (15) Thus, patients in groups 2 and 3 were unable to feel sensation during stimulation. After a protocol adjustment at 1 month, patients in the very low-intensity group were re-randomized to one of the other groups after which there were 13 patients in the standard stimulation group and 12 patients in the low-level stimulation group. At the 3-month follow-up (2 months after re-randomization), there were statistically significant between-group differences in 1 of 12 outcome variables. There were a median of 22 angina episodes in the standard stimulation group and 10 in the low-level stimulation group (p=0.002). Non-significant variables included use of nitroglycerin, quality of life (VAS), Canadian Cardiovascular Society angina class, exercise-induced angina, and 5 sub-scales of the Seattle angina questionnaire.

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Conclusions: Numerous small RCTs have evaluated SCS as a treatment for refractory angina. While some studies have reported benefit, the majority have not. In two of the larger, more recent RCTs that enrolled more than 100 patients, there was no benefit on the primary outcomes. Overall, this evidence is mixed and not sufficient to allow conclusions on whether health outcomes are improved.

Potential adverse effects

Whereas RCTs are useful for evaluating efficacy, observational studies can provide data on the likelihood of potential complications. In 2010, Mekhail and colleagues published a retrospective review of 707 patients treated with SCS between 2000 and 2005. (16) The patients' diagnoses included CRPS (n=345, 49%), failed back surgery syndrome (n=235, 33%), peripheral vascular disease (n=20, 3%), visceral pain in the chest, abdomen, or pelvis (n=37, 5%), and peripheral neuropathy (n=70, 10%). There was a mean follow-up of 3 years (range 3 months to 7 years). A total of 527 of the 707 (36%) eventually underwent permanent implantation of an SCS device. Hardware-related complications included lead migration in 119 of 527 (23%) cases, lead connection failure in 50 (9.5%) cases, and lead break in 33 (6%) cases. Revisions or replacements were done to correct the hardware problems. The authors noted that rates of hardware failure have decreased in recent years due to advances in SCS technology. Documented infection occurred in 32 of 527 (6%) patients with implants; there were 22 cases of deep infection, and 18 patients had documented abscesses. There was not a significant difference in the infection rate by diagnosis. All cases of infection were managed by device removal.

In 2012, Lanza and colleagues reviewed observational studies on SCS in patients with refractory angina pectoris. (17) The authors identified 16 studies with a total of 1,204 patients (although they noted that patients may have been included in more than one report). The most frequently reported complications were lead issues i.e., electrode dislodgement or fracture requiring repositioning, or internal programmable generator (IPG) failure during substitution. Lead issues were reported by 10 studies with a total of 450 patients. In these studies, 55 cases of lead or IPG failure were reported. No fatalities related to SCS treatment were reported.

Ongoing Clinical Trials

[Effect of Spinal Cord Stimulation in Painful Diabetic Polyneuropathy \(NCT01162993\)](#) (18): This RCT compared SCS treatment to usual care (optimal medication treatment) in patients with painful diabetic polyneuropathy in the lower limbs. Eligibility includes pain for more than 12 months and previous unsuccessful medication treatment. The primary outcome is pain intensity, and secondary endpoints include quality of life and blood glucose control. The study is sponsored by Maastricht University in the Netherlands. The expected study completion date is December 2012.

[Spinal Cord Stimulation For Heart Failure \(NCT01362725\)](#) (19): This is an observational study that will include approximately 20 patients with heart failure. Patients will be

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followed for 6 months. Primary outcomes include intra- and post-procedure adverse events, exercise capacity and functional ability, left ventricular structure and function, inflammatory condition, and quality-of-life.

Summary

In patients with refractory trunk or limb pain, the available evidence is mixed and limited by heterogeneity. Systematic reviews have found support for the use of spinal cord stimulation to treat refractory trunk or limb pain, and patients who have failed all other treatment modalities have very limited options. Therefore, spinal cord stimulation for chronic refractory pain of the trunk or limbs may be considered medically necessary when criteria are met.

For patients with critical limb ischemia, the available evidence supports a decrease in pain with a short-term decrease in limb amputations following treatment with SCS. Complications include the need for operative repositioning procedures. There is a lack of evidence for improvement in pain and limb salvage at longer endpoints, which is a crucial factor when considering a permanently implanted device. Thus, spinal cord stimulation for critical limb ischemia to reduce limb amputation is considered investigational.

For patients with refractory angina pectoris, the available evidence consists of case series and small controlled trials with methodologic limitations and limited follow-up and is not sufficient to conclude that SCS improves health outcomes. Thus, spinal cord stimulation for patients with refractory angina pectoris is considered investigational.

Practice Guidelines and Position Statements

In 2012, the Special Interest Group of the Canadian Pain Society published a guideline on interventions for neuropathic pain. (20) The guideline stated that clinicians should consider offering a trial of SCS to patients with failed back syndrome and complex regional pain syndrome who are not surgical candidates and who have failed conservative evidence-based treatments. (Recommendation based on good evidence with moderate certainty, Grade B strength of recommendation). The guideline also stated that clinicians should consider offering a trial of SCS to patients with traumatic neuropathy and brachial plexopathy who are not surgical candidates and have failed conservative evidence-based treatments. (Recommendation based on fair evidence with moderate certainty, Grade C strength of recommendation).

In 2009, the American Society of Interventional Pain Physicians updated their evidence-based guidelines for interventional techniques in the management of chronic spinal pain. (21) The guideline states that, based on Guyatt et al.'s (2006) criteria, the recommendation for spinal cord stimulation is "1B or 1C/strong recommendation for clinical use on a long-term basis" (1B is defined as 'strong recommendation, moderate

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quality evidence' and 1C as 'strong recommendation, low-quality or very low-quality evidence').

In October 2008, the National Institute for Health and Clinical Excellence (NICE) issued a guideline on spinal cord stimulation for chronic pain of neuropathic or ischemic origin. (22) The guideline stated that SCS is recommended as a treatment option for adults with chronic pain of neuropathic origin who continue to experience chronic pain (measuring at least 50 mm on a 0–100 mm VAS) 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.

An evidence-based guideline from the American Society of Interventional Pain Physicians 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. (23) Reported complications with SCS ranged from infection, hematoma, nerve damage, lack of appropriate paresthesia coverage, paralysis, nerve injury, and death.

V. DEFINITIONS[Top](#)

ARACHNOIDITIS is a chronic inflammation of the arachnoid layer of the meninges, which are the coverings of the brain and spinal cord.

DORSAL COLUMN is a part of the spinal cord which is responsible for transporting sensory input from the body to the cerebral cortex. All incoming (afferent) information to the spinal cord is conveyed via the dorsal root fibers.

VI. BENEFIT VARIATIONS[Top](#)

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital for benefit information.

VI. DISCLAIMER[Top](#)

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govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VII. REFERENCES

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1. Frey ME, Manchikanti L, Benyamin RM et al. Spinal cord stimulation for patients with failed back surgery syndrome: a systematic review. *Pain Physician* 2009; 12(2):379-97.
2. Simpson EL, Duenas A, Holmes MW et al. Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin: systematic review and economic evaluation. *Health Technol Assess* 2009; 13(17):iii, ix-x, 1-154.
3. Kumar K, Taylor RS, Jacques L et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome. *Pain* 2007; 132(1-2):179-88.
4. Kemler MA, de Vet HC, Barendse GA et al. Effect of spinal cord stimulation for chronic complex regional pain syndrome Type I: five-year final follow-up of patients in a randomized controlled trial. *J Neurosurg* 2008; 108(2):292-8.
5. Ubbink DT, Vermeulen H. Spinal cord stimulation for non-reconstructable chronic critical leg ischaemia. *Cochrane Database Syst Rev* 2005; (3):CD004001.
6. Klomp HM, Spincemaille GH, Steyerberg EW et al. Spinal-cord stimulation in critical limb ischaemia: a randomised trial. *ESES Study Group. Lancet* 1999; 353(9158):1040-4.
7. Klomp HM, Steyerberg EW, van Urk H et al. Spinal cord stimulation is not cost-effective for non-surgical management of critical limb ischaemia. *Eur J Vasc Endovasc Surg* 2006; 31(5):500-8.
8. Klomp HM, Steyerberg EW, Habbema JD et al. What is the evidence on efficacy of spinal cord stimulation in (subgroups of) patients with critical limb ischemia? *Ann Vasc Surg* 2009; 23(3):355-63.
9. Taylor RS, De Vries J, Buchser E et al. Spinal cord stimulation in the treatment of refractory angina: systematic review and meta-analysis of randomised controlled trials. *BMC Cardiovasc Disord* 2009; 9:13.
10. Borjesson M, Andrell P, Lundberg D et al. Spinal cord stimulation in severe angina pectoris--a systematic review based on the Swedish Council on Technology assessment in health care report on long-standing pain. *Pain* 2008; 140(3):501-8.
11. Mannheimer C, Eliasson T, Augustinsson LE et al. Electrical stimulation versus coronary artery bypass surgery in severe angina pectoris: the ESBY study. *Circulation* 1998; 97(12):1157-63.
12. Ekre O, Eliasson T, Norrsell H et al. Long-term effects of spinal cord stimulation and coronary artery bypass grafting on quality of life and survival in the ESBY study. *Eur Heart J* 2002; 23(24):1938-45.

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13. McNab D, Khan SN, Sharples LD et al. An open label, single-centre, randomized trial of spinal cord stimulation vs. percutaneous myocardial laser revascularization in patients with refractory angina pectoris: the SPiRiT trial. *Eur Heart J* 2006; 27(9):1048-53.
14. Zipes DP, Svorkdal N, Berman D et al. Spinal cord stimulation therapy for patients with refractory angina who are not candidates for revascularization. *Neuromodulation* 2012; 15(6):550-9.
15. Lanza GA, Grimaldi R, Greco S et al. Spinal cord stimulation for the treatment of refractory angina pectoris: a multicenter randomized single-blind study (the SCS-ITA trial). *Pain* 2011; 152(1):45-52.
16. Mekhail NA, Mathews M, Nageeb F et al. Retrospective review of 707 cases of spinal cord stimulation: indications and complications. *Pain Pract* 2011; 11(2):148-53.
17. Lanza GA, Barone L, Di Monaco A. Effect of spinal cord stimulation in patients with refractory angina: evidence from observational studies. *Neuromodulation* 2012; 15(6):542-9.
18. Sponsored by Maastricht University. *Effect of Spinal Cord Stimulation in Painful Diabetic Polyneuropathy (NCT01162993)*. Available online at: www.clinicaltrials.gov. Last accessed November, 2012.
19. Sponsored by St. Jude Medical. *Spinal Cord Stimulation For Heart Failure (NCT01362725)*. Available online at: www.clinicaltrials.gov. Last accessed November, 2012.
20. Mailis A, Taenzer P. Evidence-based guideline for neuropathic pain interventional treatments: spinal cord stimulation, intravenous infusions, epidural injections and nerve blocks. *Pain Res Manag* 2012; 17(3):150-8.
21. American Society of Interventional Pain Physicians. *Comprehensive evidence-based guidelines for interventional techniques in the management of chronic spinal pain*. Available online at: www.guideline.gov. Last accessed November, 2012.
22. National Institute for Health and Clinical Excellence (NICE). *Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin. NICE Technology Appraisal Guidance 159. October 2008.* Available online at: <http://guidance.nice.org.uk/TA159>. Last accessed November, 2012.
23. Boswell MV, Trescot AM, Datta S et al. Interventional techniques: evidence-based practice guidelines in the management of chronic spinal pain. *Pain Physician* 2007; 10(1):7-111.
24. Centers for Medicare and Medicaid Services (CMS). *National Coverage Determination for Electrical Nerve Stimulators (160.7)*. Available online at: <http://www.cms.hhs.gov>. Last accessed November, 2011.

Other Sources

Novitas Solutions. Local Coverage Determination [LCD 34705 Spinal Cord Stimulation \(Dorsal Column Stimulation\)](#) Effective 7/24/14 Assessed June 20, 2014.

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VIII. CODING INFORMATION[Top](#)

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

CPT Codes®								
63650	63655	63663	63664	63685	95970	95971	95972	95973

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HCPCS Code	Description
L8680	IMPLANTABLE NEUROSTIMULATOR ELECTRODE, EACH
L8681	PT PRGRM FOR IMPLT NEUROSTIM
L8682	IMPLANTABLE NEUROSTIMULATOR RADIOFREQUENCY RECEIVER
L8683	RADIOFREQUENCY TRANSMITTER (EXTERNAL) FOR USE WITH IMPLANTABLE NEUROSTIMULATOR RADIOFREQUENCY RECEIVER
L8685	IMPLANTABLE NEUROSTIMULATOR PULSE GENERATOR, SINGLE ARRAY, RECHARGEABLE, INCLUDES EXTENSION
L8686	IMPLANTABLE NEUROSTIMULATOR PULSE GENERATOR, SINGLE ARRAY, NON-RECHARGEABLE, INCLUDES EXTENSION
L8687	IMPLANTABLE NEUROSTIMULATOR PULSE GENERATOR, DUAL ARRAY, RECHARGEABLE, INCLUDES EXTENSION
L8688	IMPLANTABLE NEUROSTIMULATOR PULSE GENERATOR, DUAL ARRAY, NON-RECHARGEABLE, INCLUDES EXTENSION
L8689	EXTERNAL RECHARGING SYSTEM FOR BATTERY (INTERNAL) FOR USE WITH IMPLANTABLE NEUROSTIMULATOR, REPLACEMENT ONLY

ICD-9-CM Diagnosis Code*	Description
338.0	CENTRAL PAIN SYNDROME
338.21	CHRONIC PAIN DUE TO TRAUMA
338.22	CHRONIC POST-THORACOTOMY PAIN
338.28	OTHER CHRONIC POSTOPERATIVE PAIN
338.29	OTHER CHRONIC PAIN

MEDICAL POLICY

POLICY TITLE	SPINAL CORD STIMULATION
POLICY NUMBER	MP-1.069

ICD-9-CM Diagnosis Code*	Description
338.3	NEOPLASM RELATED PAIN (ACUTE) (CHRONIC)
338.4	CHRONIC PAIN SYNDROME

The following ICD-10 diagnosis codes will be effective October 1, 2015:

ICD-10-CM Diagnosis Code*	Description
G56.40-G56.42	Causalgia of upper limb code range
G57.70 - G57.72	Causalgia of lower limb code range
G89.21-G89.8	Chronic pain, not elsewhere classified, code range
G89.4	Chronic pain syndrome
G90.50-G90.59	Complex regional pain syndrome I (CRPS I), code range
M25.50- M25.579	Pain in joint, code range
M54.10- M54.18	Radiculopathy, code range
M54.30-M54.32	Sciatica, code range
M54.40-M54.42	Lumbago with sciatica, code range
M54.5	Low back pain
M54.6	Pain in thoracic spine
M54.81, M54.89	Other dorsalgia codes
M54.9	Dorsalgia, unspecified
M79.1	Myalgia
M79.60 – M79.676	Pain in limb, hand, foot, fingers and toes code range
R52	Pain, unspecified

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

MEDICAL POLICY



POLICY TITLE	SPINAL CORD STIMULATION
POLICY NUMBER	MP-1.069

IX. POLICY HISTORY

MP-1.069	CAC 7/27/04
	CAC 7/26/05
	CAC 9/27/05
	CAC 9/26/06
	CAC 9/25/07
	CAC 7/29/08
	CAC 5/26/09
	CAC 7/27/10 Consensus CAC 11-22-11 Adopt BCBSA. Added considerations for patient selection. Treatment to be used only as a last resort – failure of other treatment modalities. Pain is neuropathic in nature. No serious untreated drug habituation exists, Demonstration of at least 50% pain relief with temporarily implanted electrodes precedes permanent implantation. All facilities, equipment and professional and support personnel required for the proper diagnosis, treatment and follow-up of the patient is available. Remains medically necessary with criteria.
	7/26/13 Admin coding review complete—rsb
	CAC 9/24/13 Consensus. No change to policy statements. References reviewed and updated.
	7/24/14 Added Medicare variation to reference to LCD L34705 Spinal Cord Stimulation (Dorsal Column Stimulation)

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