

Spinal Cord Stimulation

Number: SUR712.009

Effective Date: 08-15-2014

Coverage:

Spinal cord stimulation (SCS) **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 the following criteria are met:

- Other treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) have been tried and failed, or there is documented clinical evidence that these modalities are unsuitable or contraindicated; AND
- There is no significant untreated drug habituation or addiction; AND
- There is documentation of at least 50% pain relief achieved from trial electrode implantation prior to permanent SCS implantation.

NOTE: The first two bulleted criteria (listed above) should be met to qualify for a trial electrode implantation prior to permanent SCS implantation.

NOTE: Common conditions that cause severe, chronic, refractory neuropathic pain 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 considered experimental, investigational and/or unproven** as a treatment to improve functional status of patients with other conditions that include, but are not limited to the following:

- Critical limb ischemia as a technique to forestall amputation;
- Refractory angina pectoris;
- Nociceptive pain (resulting from irritation, not damage to the nerves);
- Central deafferentation pain (related to central nervous system damage from a stroke or spinal cord injury);
- Treatment of cancer-related pain.

NOTE: For occipital nerve stimulation, see SUR712.033, Occipital Nerve Stimulation.

Description:

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.

Background

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 2 basic types of power source. In 1 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.

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 (CRPS) (i.e., 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. 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.

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 SCS 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 ItrelÒ 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.

Rationale:

This policy was originally created in 1999 and was updated regularly with searches of the MEDLINE database. The most recent literature search was performed through February 2014. Rationale was significantly revised. The 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 postlumbal surgery syndrome was undertaken by Frey et al. (1) Primary outcome measures were short term (≤ 1 year) and long-term (> 1 year) pain relief, and secondary measures were improvement in functional status, psychologic 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 1 center or research group) for clinical use of the treatment on a long term-basis.

Also in 2009, Simpson et al 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 (CRPS) 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 SCS for treating pain are described below.

A multicenter randomized trial published in 2007 by Kumar et al (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 analog 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.

In 2008, Kemler et al reported 5-year outcomes from a randomized trial of 54 patients with 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.

Section summary

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 CRPS. These studies are heterogenous 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 patients are not suitable candidates for limb revascularization (typically due to insufficient distal runoff), it is estimated that amputation will be required in a substantial number of these patients. SCS has been investigated in this 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 2013. (5) The review included RCTs and non-RCTs evaluating the efficacy of SCS in adults with nonreconstructible chronic critical leg ischemia. Six trials were identified; all were conducted in Europe and 5 were single-country studies. SCS was compared to other nonsurgical interventions. One study was nonrandomized and none were blinded.

In a pooled analysis of data from all 6 studies, there was a significantly higher rate of limb survival in the SCS group compared to the control group at 12 months (pooled risk difference [RD], -0.11; 95% confidence interval [CI], -0.20 to -0.02). The 11% difference in the rate of limb salvage means that 9 patients would need to be treated to prevent 1 additional amputation (number needed to treat, 9; 95% CI, 5 to 50). However, when the nonrandomized study was excluded, the difference in the rate of amputation no longer differed significantly between groups (RD= -0.09; 95% CI, -0.19 to 0.01). The SCS patients required significantly fewer analgesics, and more patients reached Fontaine stage II than in the control group. There was no difference in ulcer healing (but only 2 studies were included in this analysis). In the 6 studies, 31 of 210 patients (15%) had a change in stimulation requiring intervention, 8 (4%) experienced end of battery life, and there were 6 (3%) infections requiring device removal.

Previously, in 2009, Klomp et al published a meta-analysis that was limited to RCTs on SCS in patients with critical limb ischemia. (6) The same 5 RCTs identified in the Cochrane review, described above, were included. The authors did not find a statistically significant difference in the rate of amputation in the treatment and control groups. There was a relative risk of amputation of 0.79 and a risk difference of -0.07 (p=0.15). The authors 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.

Section summary

Five relatively small RCTs of SCS versus usual care have been completed on patients with critical limb ischemia. In pooled analyses of these RCTs, SCS did not result in a significantly lower rate of amputation. This evidence is not sufficient to conclude that SCS improves outcomes for patients with critical limb ischemia.

Refractory angina pectoris

SCS 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. (7) 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 SCS in severe angina pectoris was published.(8) Seven controlled studies (5 of them randomized), 2 follow-up reports, and a preliminary report, as well as 2 nonrandomized 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.(9) 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. (10) Other studies included in the Swedish systematic review include one by McNab et al from 2006, which compared SCS and percutaneous myocardial laser revascularization (PMR) in a study with 68 subjects.(11) (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 et al published an industry-sponsored, single-blind, multicenter trial with sites in the United States and Canada. (12) 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 postenrollment 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 subtherapeutic. 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). (13) 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 ($p=0.002$). Nonsignificant variables included use of nitroglycerin, quality of life (VAS), Canadian Cardiovascular Society angina class, exercise-induced angina, and 5 subscales of the Seattle angina questionnaire.

Section summary

Numerous small RCTs have evaluated SCS as a treatment for refractory angina. While some studies have reported benefit, the majority have not. In 2 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.

Cancer-related pain

In 2013, a Cochrane review by Lihua et al was published on SCS for treatment of cancer-related pain in adults.(14) The authors did not identify any RCTs evaluating the efficacy of SCS in patients with cancer-related pain. Four case series using a before-after design with a total of 92 patients were identified. In the absence of controlled studies, the efficacy of SCS for treating cancer-related pain cannot be determined.

Potential adverse effects

Whereas RCTs are useful for evaluating efficacy, observational studies can provide data on the likelihood of potential complications. In 2010, Mekhail et al published a retrospective review of 707 patients treated with SCS between 2000 and 2005. (15) 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 et al reviewed observational studies on SCS in patients with refractory angina pectoris. (16) The authors identified 16 studies with a total of 1204 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) (17): 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 end points include quality of life and blood glucose control. Estimated enrollment is 40 patients. The expected date of study completion has passed, and, as of December 2013, the study is still ongoing.

Spinal Cord Stimulation for Predominant Low Back Pain (PROMISE)(NCT01697358) (18): This multicenter open-label RCT is comparing SCS plus optimal medical management to optimal medical management alone in patients with failed back surgery syndrome who have persistent back and leg pain. The primary study outcome is the proportion of subjects with at least 50% reduction in low back pain intensity at 6 months. Estimated enrollment is 300 patients, and the expected date of study completion is April 2016.

Refractory Angina Spinal Cord and Usual Care (RASCAL) trial (19): This is a pilot RCT that is comparing SCS plus usual care to usual care alone in patients with refractory angina. The investigators aim to recruit 45 patients. The study is being conducted at 3 centers in the United Kingdom.

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 (SCS) to treat refractory trunk or limb pain, and patients who have failed all other treatment modalities have very limited options. Therefore, SCS for chronic refractory pain of the trunk or limbs may be considered medically necessary when criteria are met. For other potential indications, e.g., critical limb ischemia, refractory angina pectoris and cancer-related pain, there is insufficient evidence from controlled trials to conclude that SCS improves the net health outcome; thus, SCS is experimental investigational and unproven for these indications.

Practice Guidelines and Position Statements

In 2013, the Neuropathic Pain Special Interest Group of the International Association for the Study of Pain published recommendations on management of neuropathic pain. (20) The interest group issued 2 recommendations on SCS; both were considered weak due to the amount and consistency of the evidence. The recommendations supported the use of SCS for failed back surgery syndrome and for complex regional pain syndrome (CRPS).

In 2012, the Special Interest Group of the Canadian Pain Society published a guideline on interventions for neuropathic pain. (21) The guideline stated that clinicians should consider offering a trial of SCS to patients with failed back syndrome and CRPS 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 2013, the American Society of Interventional Pain Physicians updated their evidence-based guidelines for interventional techniques in the management of chronic spinal pain.(22) The guidelines included the statement that there is fair evidence in support of SCS in managing patients with failed back surgery syndrome.

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. (23) 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 CRPS strong for short-term relief and moderate for long-term relief. (24) Reported complications with SCS ranged from infection, hematoma, nerve damage, lack of appropriate paresthesia coverage, paralysis, nerve injury, and death.

Coding:

Disclaimer for coding information on Medical Policies

Procedure and diagnosis codes on Medical Policy documents are included only as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, device or diagnosis codes in a Medical Policy document has **no** relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a medical policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member’s benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT/HCPCS/ICD-9/ICD-10 Codes
The following codes may be applicable to this Medical policy and may not be all inclusive.
CPT Codes
63650, 63655, 63661, 63662, 63663, 63664, 63685, 63688, 95970, 95971, 95972, 95973
HCPCS Codes
L8679, L8680, L8685, L8686, L8687, L8688
ICD-9 Diagnosis Codes
Refer to ICD-9 manual
ICD-9 Procedure Codes
03.93, 03.94, 86.05, 86.94, 86.97, 86.98
ICD-10 Diagnosis Codes
Refer to ICD-10 manual
ICD-10 Procedure Codes
00HU0MZ, 00HU3MZ, 00HU4MZ , 00HV0MZ, 00HV3MZ, 00HV4MZ 00PV0MZ,

00PV3MZ, 00PV4MZ, 00WU0MZ, 00WU3MZ, 00WU4MZ, 00WV0MZ, 00WV3MZ, 00WV4MZ, 0JH60M6, 0JH60M7, 0JH60M8, 0JH60M9, 0JH63M6, 0JH63M7, 0JH63M8, 0JH63M9, 0JH70M6, 0JH70M7, 0JH70M8, 0JH70M9, 0JH73M6, 0JH73M7, 0JH73M8, 0JH73M9, 0JH80M6, 0JH80M7, 0JH80M8, 0JH80M9, 0JH83M6, 0JH83M7, 0JH83M8, 0JH83M9, 0JPT0MZ, 0JPT3MZ

Medicare Coverage:

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <<http://www.cms.hhs.gov>.

References:

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* 2013; 2:CD004001.
6. 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.
7. 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.
8. 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.
9. 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.

10. 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.
11. 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.
12. 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.
13. 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.
14. Lihua P, Su M, Zejun Z et al. Spinal cord stimulation for cancer-related pain in adults. *Cochrane Database Syst Rev* 2013; 2:CD009389.
15. 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.
16. Lanza GA, Barone L, Di Monaco A. Effect of spinal cord stimulation in patients with refractory angina: evidence from observational studies. *Neuromodulation* 2012.
17. Sponsored by Maastricht University. Effect of Spinal Cord Stimulation in Painful Diabetic Polyneuropathy (NCT01162993). Available online at: www.clinicaltrials.gov. Last accessed November, 2012.
18. Sponsored by MedtronicNeuro. Spinal Cord Stimulation for Predominant Low Back Pain (PROMISE) (NCT01697358). Available online at: www.clinicaltrials.gov. Last accessed December, 2013.
19. Eldabe S, Raphael J, Thomson S et al. The effectiveness and cost-effectiveness of spinal cord stimulation for refractory angina (RASCAL study): study protocol for a pilot randomized controlled trial. *Trials* 2013; 14:57.
20. Dworkin RH, O'Connor AB, Kent J et al. Interventional management of neuropathic pain: NeuPSIG recommendations. *Pain* 2013; 154(11):2249-61.
21. 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.
22. Manchikanti L, Abdi S, Atluri S et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. *Pain Physician* 2013; 16(2 Suppl):S49-283.
23. 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>. Last accessed December, 2013.
24. 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.

25. Lihua P, Su M, Zejun Z, Ke W, Bennett MI. Spinal cord stimulation for cancer-related pain in adults. Cochrane Database of Systematic Reviews 2013, Issue 2. Art. No.: CD009389. DOI: 10.1002/14651858.CD009389.pub2

26. Spinal Cord Stimulation. Chicago, Illinois: Blue Cross Blue Shield Association Medical Policy Reference Manual (2014 January) Surgery 7.01.25.

Policy History:

Date	Reason
8/15/2014	Document updated with literature review. Cancer related pain was added as an indication to the listing of experimental, investigational and/or unproven indications for spinal cord stimulation.
11/1/2012	Document updated with literature review. The following was added to coverage: "NOTE: The first three bulleted criteria (listed above) should be met to qualify for a trial electrode implantation prior to permanent SCS implantation".
9/15/2010	Document updated with literature review. The following change was made to coverage: List of experimental, investigational and unproven indications was revised. CPT/HCPCS codes updated.
1/15/2008	Coverage Revised
8/15/2007	Revised/Updated Entire Document
7/15/2005	Revised/Updated Entire Document
5/2000	Revised/Updated Entire Document
8/1999	New Medical Document

Archived Document(s):

Title:	Effective Date:	End Date:
Spinal Cord Stimulation	11-01-2012	08-14-2014
Implanted Spinal Cord Stimulation	09-15-2010	10-31-2012
Implanted Spinal Cord Stimulation	01-15-2008	09-14-2010
Implanted Spinal Cord Stimulation	08-15-2007	01-14-2008
Spinal Cord Stimulation	07-15-2005	08-14-2007
Spinal Cord Stimulation	08-15-2003	07-14-2005