Spinal Cord Stimulators for Pain Management

I. Description

Spinal cord stimulation delivers low voltage electrical stimulation to the dorsal columns of the spinal cord to block the sensation of 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. 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, 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 another 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 eight electrodes may be selected for those with complex pain patterns or bilateral pain. Implantation of the spinal cord stimulator is typically a two-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 percent 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.
II. Criteria/Guidelines

A. Spinal cord stimulation is covered (subject to the Limitations/Exclusions and Administrative Guidelines below) for the treatment of severe and chronic pain of the trunk or limbs that is refractory to all other pain therapies.

B. Patient selection focuses on determining whether or not the patient is refractory to other types of treatment. All of the following criteria must be met before implantation of a temporary electrode:
   1. The treatment is used only as a last resort; other treatment modalities including pharmacological, surgical, psychological, and/or physical have been tried and failed or are judged to be unsuitable or contraindicated;
   2. 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;
   3. No serious untreated drug habituation exists;
   4. Patient was carefully screened, evaluated and diagnosed by a multidisciplinary team prior to application of this therapy.

C. In addition to the above criteria, the following must be met prior to permanent implantation of the stimulator:
   1. The patient demonstrates at least 50% pain relief for one week with a temporarily implanted electrode preceding permanent implantation.

III. Limitations/Exclusions

A. Spinal cord stimulation is not covered for all other indications including but not limited to the following:
   1. Critical limb ischemia as a technique to forestall amputation.
   2. Nociceptive pain (resulting from irritation, not damage to the nerves).
   3. Central deafferentation pain (related to CNS damage from a stroke or spinal cord injury).

IV. Administrative Guidelines

A. Precertification is required before implantation of a temporary electrode AND before permanent implantation of the stimulator. To precertify, please complete HMSA's Precertification Request and mail or fax the form as indicated along with documentation demonstrating that criteria have been met.

B. The following documentation should be included with the precertification request for the implantation of a temporary electrode:
   1. Clinical notes related to the diagnosis and treatment of chronic neuropathic pain of the trunk or limbs.
   2. Documentation of all treatments tried and failed (e.g., medications, surgical notes, physical therapy notes, psychological notes, etc.).
   3. Consultation notes from a psychologist and/or psychiatrist.
C. The following must be submitted before the permanent implantation of the stimulator:
   1. The patient's pain log (e.g., diary) and physician clinical notes documenting a successful one week trial of a temporarily implanted electrode.

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<td></td>
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<td>63685</td>
<td>Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling</td>
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<td>63688</td>
<td>Revision or removal of implanted spinal neurostimulator pulse generator or receiver</td>
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V. Scientific Background
Pain (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 et al. 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. 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 SCS for treating pain are described below:
A multicenter randomized trial 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. 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.
Kemler and colleagues reported 5-year outcomes from a randomized trial of 54 patients with complex regional pain syndrome (CRPS). 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.

Summary
Although evidence is mixed and limited by heterogeneity, recent reviews have found support for the use of spinal cord stimulation to treat refractory trunk or limb pain.
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 spinal cord stimulation in peripheral vascular diseases was updated in 2005. 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 less 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 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.

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. 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.

Summary
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 no scientific evidence for improvement in pain and limb salvage at an endpoint of 24 months. Thus, spinal cord stimulation for critical limb ischemia to reduce limb amputation is considered investigational.
**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 recently been published. In 2009, Taylor et al. included seven RCTs in a systematic review of SCS in the treatment of refractory angina. 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."

The 2009 Simpson et al. systematic review, described above in the section of the Rationale on pain, summarized the evidence for SCS for refractory angina as follows: "The authors summarized their review of the evidence for SCS for refractory angina as follows: 'Evidence from angina trials suggested that SCS was more effective than No SCS or Inactive stimulator for nitrate consumption, frequency of angina attacks, exercise duration and time to angina at short term (6–8 weeks). SCS was also more effective than percutaneous myocardial revascularization (PMR) at 3 months, not at 12 months for time to angina. Health-related Quality of Life (HRQoL) was more improved by SCS than No SCS at 6–8 weeks. There was no difference between SCS and Inactive stimulator in terms of pain relief. SCS and CABG [coronary artery bypass graft] had similar results for short-acting nitrates and frequency of angina attacks. There was no difference in effectiveness of SCS and PMR for change in angina class or exercise duration. SCS did not differ from CABG or PMR or Inactive stimulator in terms of HRQoL. The SCS was less effective than CABG in reducing consumption of long-acting nitrates. SCS was less effective than CABG in increasing maximum workload capacity, although the SCS device was switched off during this comparison.

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. 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. 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. Other studies included in the Swedish systematic review include one by McNab et al., which compared SCS and PMR in a study with 68 subjects. 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.

In 2008, Bondesson and colleagues published a study comparing SCS with enhanced external counterpulsation (EECP). A total of 153 patients with refractory angina pectoris were identified, and transcutaneous electrical nerve stimulation (TENS) was used to test tolerance to electrical stimulation (except those contraindicated by unipolar pacemaker). Forty-four patients had total symptom relief and were implanted with SCS. The 79 nonresponders underwent EECP. A control group consisted of 30 patients for whom SCS or EECP were contraindicated or who were unwilling to have either treatment. Outcome measures were Canadian Cardiovascular Society Class (CCS-class) and glyceryl trinitrate (GTN) usage. At 12 months, EECP reduced CCS class from class 3 (marked limitation in activity, angina may occur after walking one block) to class 2 (slight limitation, angina may occur after walking two blocks), and 23% of the EECP group improved by 2 CCS classes. SCS reduced angina less, but the reduction was reported to be clinically significant. Of study patients who used GTN (all but 7%), decrease in weekly use was 67% of patients in the EECP group and 76% in the SCS group. A limitation of the study was there was the potential for a placebo effect because patients were not randomly assigned to treatment groups and could not be blinded to the treatment they received.

No large randomized trials on SCS for refractory angina pectoris have been published recently. A 2010 RCT from Italy included 25 patients who were randomly assigned 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). 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.

Summary
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 for patients with refractory angina pectoris. Thus, spinal cord stimulation for patients with refractory angina pectoris is considered investigational.

Technology Assessments, Guidelines, and Position Statements
In 2009, the American Society of Interventional Pain Physicians updated their evidence-based guidelines for interventional techniques in the management of chronic spinal pain. 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 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. 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. Reported complications with SCS ranged from infection, hematoma, nerve damage, lack of appropriate paresthesia coverage, paralysis, nerve injury, and death.

The European Society of Cardiology guidelines on management of stable angina pectoris do not include SCS in its list of conclusions and recommendations but state that transcutaneous electrical stimulation and SCS are “well established methods used for the management of refractory angina.” They also point out that the available clinical trials are small and long-term effects are unknown.

**Medicare National Coverage**

According to Medicare policy, the implantation of central nervous system stimulators may be covered as therapies for the relief of chronic intractable pain, subject to the following conditions:

- The implantation of the stimulator is used only as a late resort (if not a last resort) for patients with chronic intractable pain;
- With respect to item a, other treatment modalities (pharmacological, surgical, physical, or psychological therapies) have been tried and did not prove satisfactory, or are judged to be unsuitable or contraindicated for the given patient;
- Patients have undergone careful screening, evaluation, and diagnosis by a multidisciplinary team prior to implantation. (Such screening must include psychological, as well as physical evaluation.);
- All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment training, and follow-up of the patient (including that required to satisfy item c) must be available; and
- Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation.
VI. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VII. References

