Spinal Cord Stimulation

Policy

Spinal cord stimulation may be considered medically necessary for the treatment of severe and chronic pain due to failed lumbar back surgery syndrome or complex regional pain syndrome (also known as reflex sympathetic dystrophy) when ALL of the following conditions are met:

- The treatment is used 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, resulting from actual damage to the peripheral nerves.
- Member has obtained clearance by a licensed psychologist, psychiatrist or other licensed mental health professiona.
- Demonstration of at least 50% pain-relief - days with a temporarily implanted electrode and preceding permanent implantation by at least 3 days.

Spinal cord stimulation is considered investigational in all other situations, including but not limited to treatment of:

- Central deafferentation pain (related to CNS damage from a stroke or spinal cord injury).
- Nociceptive pain resulting from irritation to the nerves
- Axial back pain.
- Peripheral neuropathy.
- Critical limb ischemia as a technique to forestall amputation.
- Refractory angina pectoris.
- Post herpetic neuralgia.
- Occipital neuralgia.
- Failed cervical or thoracic surgery.

Related Policies

1.01.507 Electrical Stimulation Devices
7.01.20 Vagus Nerve Stimulation
7.01.63 Deep Brain Stimulation
### Policy Guidelines

#### Coding

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<th>CPT</th>
<th>Description</th>
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<tbody>
<tr>
<td>63650</td>
<td>Percutaneous implantation of neurostimulator electrode array, epidural</td>
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<tr>
<td>63655</td>
<td>Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural</td>
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<tr>
<td>63661</td>
<td>Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed</td>
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<tr>
<td>63662</td>
<td>Removal of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed</td>
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<tr>
<td>63663</td>
<td>Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed</td>
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<td>Revision including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed</td>
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<td>63665</td>
<td>Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling</td>
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<td>63668</td>
<td>Revision or removal of implanted spinal neurostimulator pulse generator or receiver</td>
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<td>95970</td>
<td>Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming</td>
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<td>95973</td>
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#### HCPCS

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<td>L8679</td>
<td>Implantable neurostimulator, pulse generator, any type</td>
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<td>L8680</td>
<td>Implantable neurostimulator electrode, each</td>
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<td>L8681</td>
<td>Patient programmer (external) for use with implantable programmable neurostimulator pulse generator</td>
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<td>L8682</td>
<td>Implantable neurostimulator radiofrequency receiver</td>
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<td>L8686</td>
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<td>L8687</td>
<td>Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension</td>
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<tr>
<td>L8688</td>
<td>Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension</td>
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**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 either have a power source (battery) that is surgically implanted or else the power source is worn externally and only the radiofrequency receiver is implanted.

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 (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. FDA product code: LGW.

**Scope**

Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This policy does not apply to Medicare Advantage.

**Benefit Application**
Failed Back Surgery Syndrome and Complex Regional Pain Syndrome

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).”

In 2010, Turner and colleagues sought to answer questions concerning the effectiveness and risks of SCS for chronic back and leg pain after spine surgery, also referred to as failed back surgery syndrome. This prospective, population-based controlled cohort study evaluated outcomes of workers’ compensation recipients with FBSS who received at least a trial of SCS (SCS group, n=51) versus those who were evaluated at a multidisciplinary pain clinic and did not receive SCS (Pain Clinic, n=39) or received neither SCS nor pain clinic evaluation (Usual Care, n=68). (There was an enrollment goal of 50 patients in each group but the most common reason for exclusion was leg pain not worse than back pain). Patients completed measures of pain, function, medication use, and work status at baseline and 6, 12, and 24 months later. They also examined work time loss compensation over 24 months. Few (<10%) patients in any group achieved success at any follow-up on the composite primary outcome encompassing less than daily opioid use and improvement in leg pain and function. At 6 months, the SCS group showed modestly greater improvement in leg pain and function, but with higher rates of daily opioid use. These differences disappeared by 12 months. Patients who received a permanent spinal cord stimulator did not differ from patients who received some pain clinic treatment on the primary outcome at any follow-up (<10% successful in each group at each follow-up) and 19% had them removed within 18 months. Both trial and permanent SCS were associated with adverse events. They found no evidence for greater effectiveness of SCS versus alternative treatments in this patient population after 6 months.

In 2010, Washington State Health Care Authority (HCA) Health Technology Clinical Committee contracted with Spectrum Research, Inc. to provide a technology assessment report on spinal cord stimulation. After peer review, public comments and committee discussion, HCA had the following findings: Current best evidence is available primarily from four trials on 375 patients; which are rated at a Level 1 or 2 (good quality), which is a better level of evidence than some interventions. However, total patient sample size is small, comparators were weak or inappropriate, reported outcomes are mostly subjective and not consistently reported, industry funding and management may have an impact, and no trial included a sham stimulation/procedure arm. The overall body of evidence was inconsistent, with several trials showing benefits on some outcomes at generally shorter follow up periods and others showing no difference. Given the serious limitations of the studies, the committee agreed that, at best, weak evidence exists that SCS may provide temporary improvement of pain in some patients, but there is no evidence of mid or long term pain improvement. The committee concluded that the current evidence on spinal cord stimulation demonstrates that there isn’t sufficient evidence to cover the use of spinal cord stimulation for
chronic neuropathic pain.

Hayes, Inc. issued a Medical Directory Technology Report on spinal cord stimulation in 2013. They found three randomized controlled or comparative trials for failed back surgery syndrome and one randomized trial for complex regional pain syndrome that met their study selection criteria. All four of these studies evaluated SCS for neuropathic pain. Hayes found that studies of other applications of SCS, other than for neuropathic pain, were either too small to meet selection criteria or did not include a control or comparison group. Of the studies evaluating neuropathic pain, the quality of the studies was judged to be moderate. The randomized controlled trial of SCS for CRPS and the largest randomized controlled trial for FBSS were each rated good in quality. However, none of the studies included a placebo control. The complication rate from SCS was 24% to 42% of patients. They concluded that the low number of RCTs, the small sample size of the trials and many single-site studies made it difficult to evaluate the generalizability of the results and substantial uncertainty remains about the impact on health outcomes. Nonetheless, they felt that there is some evidence that SCS can reduce chronic, refractory, neuropathic pain and may improve quality of life in patients who have failed back surgery syndrome or complex regional pain syndrome.

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. 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.

In 2008, 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.

Two European RCTs published in 2014 evaluated SCS as a treatment of painful diabetic neuropathy of the lower extremities. Both enrolled patients from pain clinics, included patients refractive to medical therapy, and compared best medical treatment with and without SCS. Slangen et al. included 36 patients, 22 were randomly assigned to SCS and 14 to continued best medical therapy. Patients in the SCS group underwent trial stimulation for 2 weeks, and 16 positive responders underwent implantation of an SCS device. Treatment success was predefined as at least a 50% reduction in pain intensity for 4 days or a score of at least 6 on a 7 point Likert scale (1 = very much worse and 7 = very much improved). In an intention-to-treat analysis conducted after 6 months of treatment, 59% in the SCS group and 7% in the usual care group were considered treatment successes (p<0.01). Seven patients in the SCS group and none in the usual care group reduced their use of pain medication. Two patients in the SCS group experienced a serious adverse event; 1 infection and 1 postdural puncture headache in the test stimulation phase.

de Vos et al. randomized 40 patients to SCS and 20 to best medical therapy. After a maximum of 7 days of trial stimulation, 37 patients in the SCS group underwent device implantation. Fifty-four patients completed the 6-month follow-up; analysis was intention to treat. The primary outcome, more than 50% pain relief at 6 months, was achieved by 25 of 40 (62.5%) patients in the SCS group and 1 of 20 (5%) in the control group (p-value not reported). Mean scores on a 100-point VAS decreased from 73 to 31 in the SCS group and remained at 67 in the control group. Both of the studies had dramatic findings in favor of SCS; however, both had only 6 months of follow-up.

**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 for these conditions only.

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 2013. The review included RCTs and non-RCTs evaluating the efficacy of SCS in adults with non-reconstructable 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.

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.

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
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 7 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. from 2006, 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.

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. 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.

In 2008, Bondesson and colleagues published a non-randomized 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 2 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.

A small 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). 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.

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 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.

Heart Failure
Findings of a small pilot crossover RCT evaluating SCS for heart failure were published in 2014 by Torre-Amione et al. Eligibility included symptomatic heart failure despite optimal medical therapy, left ventricular ejection fraction less than 30%, hospitalization or need for intravenous inotropic support in the past year, and ability to walk less than 450 meters on a 6-minute walk test. All patients had an implanted heart device. Nine patients underwent SCS implantation and received 3 months of active treatment and 3 months of inactive treatment (off position), in random order. There was a 1-month washout period between treatments. The primary outcome was a composite of death, hospitalization for worsening heart failure, and symptomatic bradyarrhythmia or tachyarrhythmia requiring high-voltage therapy. Four patients experienced at least 1 of the events in the composite end point. The event occurred in 2 patients while the device was turned on and 2 while it was turned off. One patient died about 2 months after implantation while the device was turned off. The SCS devices did not interfere with the functioning of implantable cardioverter defibrillators. Additional RCTs with larger sample sizes and longer follow-up are needed to draw conclusions on the safety and effectiveness of the therapy for this indication.

Cancer-related Pain
In 2013, a Cochrane review by Lihua et al. was published on SCS for treatment of cancer-related pain in adults. 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 and colleagues published a retrospective review of 707 patients treated with SCS between 2000 and 2005. 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. 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. The authors noted that rates of hardware failure have decreased in recent years due to advances in SCS technology.

In 2012, Lanza and colleagues reviewed observational studies on SCS in patients with refractory angina pectoris. 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

**Spinal Cord Stimulation for Predominant Low Back Pain (PROMISE) (NCT01697358):**
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:**
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 failed back surgery syndrome or complex regional pain syndrome, and patients who have failed all other treatment modalities have very limited options. Therefore, SCS for failed back surgery syndrome or complex regional pain syndrome may be considered medically necessary when criteria are met. For other potential indications, eg, 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 investigational for these indications.

Practice Guidelines and Position Statements
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.

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

In 2013, the Neuropathic Pain Special Interest Group of the International Association for the Study of Pain published recommendations on management of neuropathic pain. 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).

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. Reported complications with SCS ranged from infection, hematoma, nerve damage, lack of appropriate paresthesia coverage, paralysis, nerve injury, and death.

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.

References

19. Mekhail NA, Mathews M, Nageeb F et al. Retrospective review of 707 cases of spinal cord stimulation:

Appendix
N/A

History

Date Reason
04/10/12 New policy replacing 7.01.25.
07/20/12 Clarification made to first policy statement; pain is defined in single nerve-root distribution change to lumbosacral nerve root distribution, as approved by MPC on April 10, 2012.
08/27/12 Update Related Policies – Add 7.01.20. Update Coding Section – ICD-10 codes are now effective 10/01/2014.
04/16/13 Replace policy. No change to policy statements. References 14, 18, 21, 22 added.
12/19/13 Update Related Policies. Remove 1.01.19 as it was archived.
07/14/14 Annual Review. Policy statement revised. Spinal cord stimulation may now be considered medically necessary for pain due to complex regional pain syndrome when criteria are met. “Lumbar” added as clarification to failed back surgery syndrome and criteria revised. Rationale extensively updated. References added.
03/31/15 Annual Review. Policy statements unchanged. Policy updated with literature review through December 2014. References 5. 6, 16 added. Remove ICD-9 codes 03.93, 03.94, 86.05, 86.09 and 86.94, along with associated ICD-10 codes; these do not suspend and are informational only.
05/27/15 Coding update; ICD-9 procedure code 86.96 added to policy; ICD-10 PCS codes adding per cross walk remediation.
01/29/16  Coding update. Added HCPCS code L8679.
04/12/16  Annual review. Clarified policy statement adding, licensed mental health provider. No new references added.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA).
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