Spinal Cord and Dorsal Root Ganglion Stimulation

Policy Number: 7.01.25
Origination: 10/1988
Last Review: 10/2019
Next Review: 10/2020

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for Spinal Cord Stimulation when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered
Spinal cord stimulation with standard or high-frequency stimulation may be considered **medically necessary** for the treatment of severe and chronic pain of the trunk or limbs that is refractory to all other pain therapies, when performed according to policy guidelines.

Patient selection focuses on determining whether or not the patient is refractory to other types of treatment. The following considerations may apply.

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

Dorsal root ganglion neurostimulation is 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 performed according to policy guidelines.
When Policy Topic is not covered
Spinal cord stimulation is considered investigational in all other situations including but not limited to treatment of critical limb ischemia to forestall amputation and treatment for refractory angina pectoris, heart failure, and cancer-related pain.

Considerations
“Burst” neurostimulation is an alternate programming of a standard SCS device. A clinician programmer application is used to configure a standard SCS device to provide stimulation in “bursts” rather than at a constant (“tonic”) rate.

Coding
In 2016, a HCPCS “C” code was issued for high-frequency neurostimulator generator:

C1822 Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system.

The Centers for Medicare & Medicaid Services has issued instructions that the existing implantable neurostimulator code C1820 should only be used for stimulators that are not high frequency.

Description of Procedure or Service

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
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</table>
| Individuals:  
- With treatment-refractory chronic pain of the trunk or limbs | Interventions of interest are:  
- Standard spinal cord stimulation | Comparators of interest are:  
- Medical therapy  
- Surgical therapy | Relevant outcomes include:  
- Symptoms  
- Functional outcomes  
- Quality of life  
- Medication use  
- Treatment-related morbidity |
| Individuals:  
- With treatment-refractory chronic pain of the trunk or limbs | Interventions of interest are:  
- High-frequency spinal cord stimulation | Comparators of interest are:  
- Standard spinal cord stimulation  
- Medical therapy  
- Surgical therapy | Relevant outcomes include:  
- Symptoms  
- Functional outcomes  
- Quality of life  
- Medication use  
- Treatment-related morbidity |
| Individuals:  
- With treatment-refractory chronic pain of the trunk or limbs | Interventions of interest are:  
- Dorsal root ganglion neurostimulation | Comparators of interest are:  
- Standard spinal cord stimulation  
- Medical therapy  
- Surgical therapy | Relevant outcomes include:  
- Symptoms  
- Functional outcomes  
- Quality of life  
- Medication use  
- Treatment-related morbidity |
| Individuals:  
- With critical limb ischemia | Interventions of interest are:  
- Spinal cord | Comparators of interest are:  
- Medical therapy | Relevant outcomes include:  
- Overall survival |
Spinal cord stimulation (SCS) delivers low-voltage electrical stimulation to the dorsal columns of the spinal cord to block the sensation of pain; this is achieved through a surgically implanted SCS device, which comes equipped with a radiofrequency receiver. The neurostimulator device is also issued with a standard power source (battery) that can be implanted or worn externally. Other neurostimulators target the dorsal root ganglion.

**Treatment-Refractory Chronic Pain**

For individuals who have treatment-refractory chronic pain of the trunk or limbs who receive standard SCS, the evidence includes systematic reviews and randomized controlled trials (RCTs). The relevant outcomes are symptoms, functional outcomes, quality of life (QOL), medication use, and treatment-related morbidity. Available RCTs are heterogeneous regarding underlying diagnoses in select patient populations. However, the trials including patients with underlying neuropathic pain processes have shown a significant benefit with SCS. Systematic reviews have supported the use of SCS to treat refractory trunk or limb pain, and patients who have failed all other treatment modalities have few options. The

<table>
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<th>Interventions of interest are:</th>
<th>Comparators of interest are:</th>
<th>Relevant outcomes include:</th>
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<tr>
<td>With treatment-refractory angina pectoris</td>
<td>Spinal cord stimulation</td>
<td>Medical therapy</td>
<td>Overall survival</td>
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<td>Coronary revascularization</td>
<td>Symptoms</td>
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<td>Functional outcomes</td>
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<td>Treatment-related morbidity</td>
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Spinal cord and Dorsal Root Ganglion Stimulation 7.01.25
For individuals who have treatment-refractory chronic pain of the trunk or limbs who receive high-frequency SCS, the evidence includes three RCTs. The relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. One RCT comparing high-frequency with standard SCS in patients who had not previously been treated with SCS found a clinically and statistically significant benefit associated with high-frequency SCS. Another RCT in patients who had chronic pain despite previous treatment with standard SCS found no benefit for those receiving high-frequency stimulation compared with sham-control; however, it is difficult to compare these findings with other trials of SCS due to the different patient populations, short treatment periods, and the crossover period effect. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have treatment-refractory chronic pain of the trunk or limbs who receive dorsal root ganglion (DRG) neurostimulation, the evidence includes an RCT and many case series. The relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. The unblinded RCT found that patients receiving DRG neurostimulation had significantly higher rates of treatment success (physical functioning score and QOL measures), at 3 and 12 months compared with those receiving standard SCS devices. DRG neurostimulation was found to be noninferior to SCS in percentage achieving ≥50% pain reduction, emotional functioning score, and 36-Item Short-Form Health Survey scores. Both groups experienced paresthesias but patients in the DRG group reported less postural variation in paresthesia and reduced extraneous stimulation in nonpainful areas. Rates of serious adverse events were similar between the two study arms. While most of the case series were small (sample sizes ranged from 10 to 65), all reported results that were consistent with the RCT results. The largest case series had the longest follow-up, reporting continued improvements in pain and psychological scores through three years. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

**Critical Limb Ischemia**

For individuals who have critical limb ischemia who receive SCS, the evidence includes RCTs. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. In some pooled analyses of these RCTs, SCS did not result in a significantly lower rate of amputation, although a systematic review and meta-analysis did report a significant difference. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Treatment-Refractory Angina Pectoris**

For individuals who have treatment-refractory angina pectoris who receive SCS, the evidence includes RCTs. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and
treatment-related morbidity. Numerous small RCTs have evaluated SCS as a treatment for refractory angina. While some have reported benefit, most have not. In 2 more recent RCTs, there was no significant benefit on the primary outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Heart Failure**
For individuals who have heart failure who receive SCS, the evidence includes RCTs. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. One small pilot crossover study (N=9) reported at least 1 adverse event in 2 patients with the device turned on and in 2 patients with the device turned off. A sham-controlled randomized trial (N=66) did not find significant differences between groups but might have been underpowered to do so. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Cancer-Related Pain**
For individuals who have cancer-related pain who receive SCS, the evidence includes no RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. No RCTs evaluating SCS in this population were identified. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Background**
**Chronic Pain**
Spinal cord stimulation (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 (ie, 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.

**Spinal Cord Stimulation**
SCS—also called dorsal column stimulation—involves the use of low-level epidural electrical stimulation of the spinal cord dorsal columns. 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.

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 electricity. The lead may incorporate from four to eight electrodes, with eight electrodes more commonly used for complex pain patterns. There are two basic types of power source: one type, the power source (battery), can be surgically implanted or worn externally with an antenna over the receiver; the other, a radiofrequency receiver, is implanted. Totally implantable systems are most commonly used.
The patient's pain distribution pattern dictates at what level of 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 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.

Traditional SCS devices use electrical stimulation with a frequency of 100 to 1000 Hz. In 2015, an SCS device, using a higher frequency (10000 Hz) than predicate devices, was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. High-frequency stimulation is proposed to be associated with fewer paresthesias, which are a recognized effect of SCS. In 2016, the FDA approved a clinician programmer application that allows an SCS device to provide stimulation in bursts rather than at a constant rate. Burst stimulation is proposed to relieve pain with fewer paresthesias. The burst stimulation device works in conjunction with standard SCS devices. With the newly approved app, stimulation is provided in five, 500-Hz burst spikes at a rate of 40 Hz, with a pulse width of 1 ms.

The incidence of adverse events related to spinal cord stimulation have been reported to occur in 30% to 40% of cases. Adverse events can either be hardware-related or biological. Hardware-related complications include lead migration or lead failure or fracture. Biological complications include infection and pain. More severe biological complications are rare, including dural puncture headache (estimated incidence, up to 0.3%) and neurological damage (estimated incidence, 0.25%).

Other neurostimulators target the dorsal root ganglion (DRG). Dorsal root ganglia consists of sensory cell bodies that transmit input from the peripheral nervous system to the central nervous system, and play a role in neuropathic pain perception. Dorsal root ganglia are located in the epidural space between spinal nerves and the spinal cord on the posterior root in a minimal amount of cerebrospinal fluid, amenable to epidural access. Two systems targeting the DRG have received approval or clearance from the FDA.

A retrospective analysis of the FDA's Manufacturer and User Facility Device Experience (MAUDE) database provided information on complications related to the use of DRGstimulation. The MAUDE database was queried for DRG stimulation reports through 2017, identifying 979 episodes. Complications were predominantly device-related (47%; lead migration and lead damage), with the remaining comprised of procedural complications (28%; infection, new neurologic symptoms, and dural puncture), patient complaints (12%; site pain and unwanted stimulation), serious adverse events (2.4%), and "other" complications (4.6%). The prevalence of complications cannot be estimated using the MAUDE
database; while facilities are mandated to report events, patients and health care providers may report events but are not mandated to do so.

**Outcome Measures**
The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials group has provided recommendations for four core chronic pain outcome domains that should be included when selecting outcome measures for clinical trials of treatments for chronic pain: (1) pain intensity; (2) physical functioning; (3) emotional functioning; and (4) participant ratings of overall improvement. The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials has also suggested specific outcome measures to address these core domains and has proposed provisional benchmarks for identifying clinically important changes in these specific outcome measures (see Table 1).

**Table 1. Health Outcome Measures Relevant to Trials of Chronic Pain**

<table>
<thead>
<tr>
<th>Domain</th>
<th>Outcome Measure</th>
<th>Description</th>
<th>Clinically Meaningful Difference</th>
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| Pain intensity        | • Numeric rating scale                                                        | Rating of pain intensity on a scale of 0 (no pain) to 10 (pain as bad as you can imagine) or from 0 to 10 cm      | • Minimally important: 10%-20% decrease  
                          • Verbal rating scale                                                          |                                                                                  | • Moderately important: ≥30% decrease  
                          • Visual analog scale                                                          |                                                                                  | • Substantial: ≥50% decrease          |
| Physical functioning  | Disease specific                                                              | Measures of the interference of pain with physical functioning                                                   |                                  |
|                       | • Multidimensional Pain Inventory Interference Scale                          | • 60 items, self-report                                                                                           | • ≥0.6-point decrease            |
|                       |                                                                                | • 12 subscales: interference, support, pain severity, self-control, negative mood, punishing responses, solicitous responses, distracting responses, household chores, outdoor work, activities away from home, and social activities  
<p>|                       |                                                                                | • Items rated on 0- to 6-point scale                                                                             |                                  |</p>
<table>
<thead>
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<th>Domain</th>
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|                 | • Brief Pain Inventory<sup>7</sup> Interference Scale | • 7 items, self-report  
• Measures intensity, quality, relief and interference of pain and patients' ideas of the causes of pain  
• Mean of the 7 interference items can be used as a measure of pain interference | • 1-point decrease<sup>5</sup>. |
|                 | • Oswestry Disability Index<sup>8</sup>              | Measures functional impairment due to lower back pain:  
• 10 sections, self-report  
• Sections: intensity of pain, lifting, ability to care for oneself, ability to walk, ability to sit, sexual function, ability to stand, social life, sleep quality, and ability to travel  
• Each section is scored on a 0 to 5 scale with 5 indicating the greatest disability  
• Total score calculated by taking the mean of the section scores and multiplying by 100 | • 10 points<sup>9</sup>. |
| General         | Generic measure of physical functioning              |                                                                                                                                                                                                          |                                  |
|                 | • 36-Item Short Form Health Survey                    | Measure overall health status:  
• 36 items, self-report  
• 8 domains: physical function, physical role, general health, bodily pain, mental health, social function, vitality/fatigue, and emotional role  
• Physical Component Summary and Mental Component Summary scores | • 5-10 points<sup>10,11,12</sup>. |
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<th>Clinically Meaningful Difference</th>
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<td></td>
<td>are aggregate scores that can be calculated</td>
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<td>• Higher scores indicate better health status</td>
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<td>Emotional functioning</td>
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<td></td>
<td>• Beck Depression Inventory[14]</td>
<td>• 21 items, self-report</td>
<td>• ≥5-point decrease[5].</td>
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<td>• Measures severity of current symptoms of depressive disorders</td>
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<td>• Scores range from 0 to 63</td>
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<td>• Profile of Mood States[14]</td>
<td>• 65 items, self-report</td>
<td>• ≥10- to 15-point decrease[5].</td>
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<td>• Measures total mood disturbance with 6 subscales: tension, depression, anger</td>
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<td>• vigor, fatigue, and confusion</td>
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<td>• Scores range from 0 to 200</td>
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<td>Global rating of improvement</td>
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<td></td>
<td>• Patient Global Impression of Change</td>
<td>• Single-item, self-rating</td>
<td>• Minimally important: minimally improved</td>
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<td>• 7-point scale ranging from 1 (very much worse) to 7 (very much improved)</td>
<td>• Moderately important: much improved</td>
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<td>• Substantial: very much improved[5].</td>
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(FBSS), intractable low back pain, and leg pain."\textsuperscript{15} This device uses a higher frequency of electrical stimulation (10 kHz) than standard devices.

In February 2016, the Axium Neurostimulator System (Abbott) was approved by the FDA through the premarket approval process. This implanted device stimulates the DRG. Further, it is indicated as an aid in the management of moderate-to-severe intractable pain of the lower limbs in adults with complex regional pain syndrome types I and II.

In August 2016, the Freedom Spinal Cord Stimulator (Stimwave Technologies), a wireless injectable stimulator, was cleared for marketing by the FDA through the 510(k) process for treating chronic, intractable pain of the trunk and/or lower limbs. The Freedom device has implantable or injectable microstimulators that contain electrode(s). The microstimulators with electrodes are powered by a wireless battery pack worn externally. The device can be placed to target the spinal cord (ie, levels T7 to L5) or to target the dorsal root ganglion.

In October 2016, the FDA approved BurstDR™ stimulation (St. Jude Medical), a clinician programmer application that provides intermittent "burst" stimulation for patients with certain St. Jude SCS devices.

In August 2017, the PrecisionTM Spinal Cord Stimulator (Boston Scientific) was approved by the FDA through the premarket approval process.

**Rationale**

This evidence review was created in March 1996 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through March 20, 2019.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances,
nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

**Spinal Cord and Dorsal Root Ganglion Stimulation**

**Clinical Context and Therapy Purpose**

The purpose of SCS and DRG stimulation in patients who have treatment refractory chronic pain, critical limb ischemia, angina pectoris, heart failure, or cancer-related pain, is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of SCS or DRG stimulation improve the net health outcomes of patients with treatment refractory chronic pain, critical limb ischemia, angina pectoris, heart failure, or cancer-related pain compared with medical and surgical therapies?

The following PICO were used to select literature to inform this review.

**Patients**

There are several populations of interest in this review:
- Patients with treatment-refractory chronic pain of the trunk or limbs
- Patients with critical limb ischemia
- Patients with treatment-refractory angina pectoris
- Patients with heart failure
- Patients with cancer-related pain

**Interventions**

The therapies being considered include:
- **SCS**: SCS uses low-level epidural electrical stimulation of the spinal cord dorsal columns. There mechanism of action is uncertain but may be related to either activation of an inhibitory system or blockage of facilitative circuits. SCS devices consist of several components: (1) the lead delivering 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. The lead may incorporate four to eight electrodes, depending on the complexity of the pain pattern. A trial period in which the electrode is temporarily implanted in the epidural space is recommended, prior to the permanent implantation. Most SCS devices operate under a frequency of 100 to 1000 Hz.
- **High-frequency spinal cord stimulation (HFSCS)**: HFSCS devices use a higher frequency (10000 Hz) compared with the standard SCS devices. HFSCS potentially lowers the incidence of paresthesias compared with standard SCS.
- **DRG neurostimulation**: DRG uses the same epidural approach technique as SCS but targets a different anatomical target, the DRG.
Comparators

The standard of care, by population of interest consists of:
- Patients with treatment-refractory chronic pain of the trunk or limbs: medical therapy or surgical therapy
- Patients with critical limb ischemia: medical therapy or surgical therapy (revascularization surgery or amputation)
- Patients with treatment-refractory angina pectoris: medical therapy or coronary revascularization
- Patients with heart failure: medical therapy or coronary revascularization
- Patients with cancer-related pain: medical therapy

Outcomes

The general outcomes of interest include reduction in pain symptoms and improvements in QOL.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Refractory Chronic Trunk or Limb Pain

Standard Spinal Cord Stimulation

Systematic Reviews

Existing RCTs of standard SCS for chronic trunk or limb pain are summarized in the next section. Five systematic reviews have assessed the RCTs included in the next section and overlap substantially. The North et al (2005)\textsuperscript{16}, and Kumar et al (2007)\textsuperscript{17}, RCTs are included in 3 systematic reviews; Kemler et al (2000)\textsuperscript{16} is included in 3 reviews, and Kapural et al (2015)\textsuperscript{18}, included in 1 of the systematic reviews.

Two systematic reviews have focused on SCS specifically for complex regional pain syndrome (CRPS). Visnjevac et al (2017) reported on results of a systematic review of RCTs and observational studies of SCS for CRPS.\textsuperscript{19} The Kemler et al (2000) trial was the only RCT included and it is discussed in the following section. The Cochrane overview of systematic reviews by O'Connell et al (2013) also focused on reviews of CRPS.\textsuperscript{20} The overview included reports from the Kemler et al (2000) RCT. Reviewers concluded that there was very low-quality evidence using GRADE criteria that SCS using physical therapy was effective at
reducing pain or improving QOL in CRPS compared with physical therapy alone for up to two years.

Grider et al (2016) reported on results of a systematic review of RCTs of SCS for chronic spinal pain.[21] Six RCTs meeting selection criteria were identified; three RCTs reported on the efficacy of standard SCS, while three assessed adaptive stimulation, HFSCS (discussed below), and burst stimulation. Of the three RCTs assessing standard SCS, two were considered high-quality and one moderate-quality based on Cochrane criteria and Interventional Pain Management Techniques-Quality Appraisal of Reliability and Risk of Bias Assessment. Kapural et al (2015) is discussed below in the section on HFSCS. In the North et al (2005) and Kumar et al (2007) RCTs, SCS was associated with higher rates of pain relief than the comparator groups.

Two systematic reviews have focused on SCS for failed back surgery syndrome (FBSS), defined as persistent pain after spinal surgery and the initial pain may have been secondary to various causes. Kapural et al (2017) reported on a systematic review of prospective studies of SCS for FBSS.[22] The North et al (2005) and Kumar et al (2007) trials were the only RCTs included and are discussed in the following section. A systematic review of RCTs and observational studies evaluating SCS for FBSS was conducted by Frey et al (2009).[23] The 2 RCTs by North et al (2005) and Kumar et al (2007) were included. Using the U.S Preventive Services Task Force quality ratings, reviewers 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 >1 center or research group) for the clinical use of standard SCS on a long-term basis.

Also, Simpson et al (2009) reported on a health technology assessment, funded by the National Institute for Health and Care Excellence, to obtain clinical and cost-effectiveness data for SCS in adults with chronic neuropathic or ischemic pain with inadequate response to other medical or surgical treatments.[24] The Institute used the assessment as the basis for its guidance on SCS for chronic pain.[25] Trials for FBSS and CRPS type I (reported by North et al [2005],[16] Kumar et al [2007],[17] and Kemler et al [2000, 2004][26,27]) suggested that SCS was more effective than conventional medical management or reoperation in reducing pain.

Randomized Controlled Trials
Six RCTs (total n=528 patients; range, 36-218 patients) have evaluated SCS (see Table 2). Patient populations had FBSS, diabetic neuropathy, and CRPS. The comparators were primarily conventional medical management, although one RCT compared CSC with reoperation for FBSS, and another compared SCS with physical therapy. All RCTs reported results at six months. The most common primary outcome reported was a responder outcome of 50% reduction in pain; Kemler et al (2000) reported absolute change in visual analog scale (VAS) pain score.[26] Consistent with clinical practice, RCTs included a trial period of SCS, usually a few days to a week. Patients not reporting improvement in pain during the trial period did not continue receiving SCS during the remainder of follow-up. In most RCTs, these patients were included in the intention-to-treat analyses.
either as failures to respond or using imputation techniques. All RCTs with the responder primary outcomes reported clinically and statistically significant differences in the primary outcomes at 6 months, favoring SCS (SCS range, 39%-63% vs comparator range, 5%-12%). Outcomes measuring the reduction in analgesic use were consistently numerically larger for SCS but not statistically significant in all studies. Four of the five studies did not report differences in functional, QOL, or utility outcomes. Device-related complications ranged from 17% to 32%, with the most common being infection and discomfort or pain due to positioning or migration of electrodes or leads. However, 2 studies reported dural puncture headaches and Slangen et al (2014) reported a dural puncture headache ending in death. Two studies reported longer term results for both treatment groups. In each, results continued to favor SCS at two years, but for one with five years of follow-up, results were not statistically significant at five years.

Section Summary: Standard SCS for Refractory Chronic Trunk or Limb Pain
The evidence on the efficacy of standard SCS for the treatment of chronic limb or trunk pain consists of a number of RCTs evaluating patients with refractory pain due to FBSS, CRPS, or diabetic neuropathy. These trials were heterogenous regarding patient populations and participants were unblinded (no trials used sham surgeries or devices) but they consistently reported reductions in pain, with clinically and statistically significant effect sizes and reductions in medication use for at least six months. Even with a sham-controlled surgery or device, blinded outcomes assessment may not be feasible for SCS because active SCS stimulation is associated with paresthesias. Given the extensive treatment effects with consistent findings across studies, this evidence suggests that SCS is a reasonable treatment option.

High-Frequency SCS
In 2015, an SCS device, using a higher frequency of electrical stimulation (10 kHz) than predicate devices (which use frequencies on the order of 100-1000 Hz), was approved by the U.S. Food and Drug Administration. Studies that offer direct comparisons between standard SCS and HFSCS were sought to evaluate the incremental benefit of HFSCS.

Systematic Reviews
Bicket et al (2016) published a systematic review of controlled trials on HFSCS. Reviewers searched for RCTs and controlled nonrandomized studies of adults with pain for at least 3 months who were treated with HFSCS (ie, ≥1000 Hz) and prospectively assessed pain outcomes. Eight studies met these inclusion criteria; two RCTs (detailed below) and six controlled nonrandomized studies. Both RCTs and five of six controlled studies addressed low back pain; the remaining controlled study addressed migraine. Reviewers used the Cochrane criteria to rate bias in the RCTs. One trial (Perruchoud et al [2013]) was not rated as having a high-risk of bias in any domain, and the other (Kapural et al [2015]) was rated as having a high-risk of bias in the domain of performance and detection
bias because it was unblinded. Studies were reviewed qualitatively (ie, study findings were not pooled).

Table 2. Characteristics and Result of RCTs Using Standard SCS

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Interventions</th>
<th>N at Baseline and Follow-Up</th>
<th>Results</th>
<th>Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>North et al (2005)18</td>
<td>FBSS</td>
<td>SCS + CMM + Reoperation + CMM</td>
<td>N=60 at 6 mo=49</td>
<td>Success (50% pain relief and patient satisfaction)</td>
<td>17% device-related complications (infections, hardware technical problems)</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>39%</td>
<td>12%</td>
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<td></td>
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<td>Stable or decreased opioids</td>
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<td></td>
<td></td>
<td></td>
<td>No difference in ADLs impairment due to pain</td>
<td></td>
</tr>
<tr>
<td>Kumar et al (2007, 2008)17 31</td>
<td>FBSS with neuropathic pain</td>
<td>SCS + CMM + CMM</td>
<td>N=100 at 6 mo=93</td>
<td>50% reduction in VAS leg pain</td>
<td>32% device-related complications (electrode migration, infection, loss of paresthesia)</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td>48%</td>
<td>9%</td>
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<td>SF-36, favoring SCS all domains except RP</td>
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<td></td>
<td>ODI score</td>
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<td></td>
<td>Opioid use</td>
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<td></td>
<td></td>
<td>NSAID use</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>n at 24 mo=87</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Population</td>
<td>Interventions</td>
<td>N at Baseline and Follow-Up</td>
<td>Results</td>
<td>Complications</td>
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<tr>
<td>Kemler et al (2000, 2004, 2008)</td>
<td>CRPS</td>
<td>SCS + PT</td>
<td>n=54 at 6 mo=54 (SCS vs PT)</td>
<td>50% reduction in leg pain on VAS</td>
<td>37% 2% 0.003</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PT</td>
<td></td>
<td>37% 2% 0.003</td>
<td>2% 0.003</td>
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<td></td>
<td>50% reduction in leg pain on VAS</td>
<td>37% 2% 0.003</td>
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<td></td>
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<td></td>
<td>Reduction in VAS pain score</td>
<td>2.4 0.2 &lt;0.001</td>
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<tr>
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<td></td>
<td>Much improved GPE</td>
<td>39% 6% 0.01</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No difference in functional outcomes or HRQOL</td>
<td>2 y (SCS vs PT)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Reduction in VAS pain score</td>
<td>2.1 0.0 &lt;0.001</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Much improved GPE</td>
<td>43% 6% 0.001</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Reduction in VAS pain score</td>
<td>1.7 1.0 0.25</td>
</tr>
<tr>
<td>Slange et al (2014)</td>
<td>Diabetic neuropathy of LEs</td>
<td>SCS</td>
<td>n=36 at 6 mo=36 (SCS vs CMM)</td>
<td>50% reduction in leg pain on VAS</td>
<td>37% 2% 0.003</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMM</td>
<td></td>
<td>Reduction in VAS pain score</td>
<td>1.7 1.0 0.25</td>
</tr>
<tr>
<td>Study</td>
<td>Population</td>
<td>Interventions</td>
<td>N at Baseline and Follow-Up</td>
<td>Results</td>
<td>Complications</td>
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<tr>
<td></td>
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<td></td>
<td>50% reduction in pain for 4 d or at least much improved on patient-reported global impression of change</td>
<td>59%</td>
<td>7%</td>
</tr>
<tr>
<td></td>
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<td>Reduction in pain medication</td>
<td>32%</td>
<td>0%</td>
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<td></td>
<td></td>
<td></td>
<td>No differences in health utility or HRQOL</td>
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<tr>
<td>De Vos et al (2014)(^3), Duarte et al (2016)(^4)</td>
<td>Diabetic neuropathy of LEs</td>
<td>SCS, CMM</td>
<td>N=60 at 6 mo=54</td>
<td>Success 65%</td>
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<td></td>
<td></td>
<td></td>
<td>50% reduction in pain</td>
<td>62.5%</td>
<td>5%</td>
</tr>
<tr>
<td>Study</td>
<td>Population</td>
<td>Interventions</td>
<td>N at Baseline and Follow-Up</td>
<td>Results</td>
<td>Complications</td>
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</tr>
<tr>
<td></td>
<td>FBSS</td>
<td>• SCS + CMM</td>
<td>N=218 at 6 mo=116</td>
<td>Reduction in analgesic intake (MQS score)</td>
<td>2.9 -0.09 NR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• CMM</td>
<td></td>
<td>• Change in health utility</td>
<td>0.39 0.00 &lt;0.05</td>
</tr>
<tr>
<td>Rigoard P</td>
<td>FBSS</td>
<td></td>
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<td></td>
<td>18% device-related complications, with 12% requiring surgical re-intervention</td>
</tr>
<tr>
<td>(2019)</td>
<td>FBSS</td>
<td>• SCS + CMM</td>
<td>N=218 at 6 mo=116</td>
<td>50% reduction in pain</td>
<td>14% 5% 0.04</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• CMM</td>
<td></td>
<td>• Change in SF-36 Short Form</td>
<td>7.5 0 &lt;0.001</td>
</tr>
</tbody>
</table>

ADL: activities of daily living; CMM: conventional medical management; CRPS: complex regional pain syndrome; ctrl: control; FBSS: failed back surgery syndrome; GPE: global perceived effect; HRQOL: health-related quality of life; Int: intervention; LE: lower extremities; MQS: Medication Quantification Scale III; NR: not reported; NSAID: non-steroidal anti-inflammatory drug; ODI: Oswestry Disability Index; PCS: Physical Component Summary; PT: physical therapy; RP: role-physical; SAE: serious adverse events; SCS: spinal cord stimulation; SF-36: 36-Item Short-Form Health Survey; VAS: visual analog scale; RCT: randomized controlled trial.

a SCS only.

Randomized Controlled Trials

Three RCTs identified addressed HFSCS (see Table 3): Perruchoud et al (2013) compared HFSCS (5000 Hz) with sham-control in a crossover design (n=40), while Kapural et al (2015)18 (n=198) and De Andres et al (2017)33 (n=60) both compared HFSCS (10000 Hz) with standard SCS. The three trials had distinct patient populations and designs such that the results could not be synthesized.

The Perruchoud et al (2013) population was distinct from other trials of SCS or HFSCS in that it included patients who had chronic, treatment-refractory back pain previously treated with standard SCS (ie, patients were not treatment-naive to SCS).30 This trial used a 2×2 crossover design with a run-in and washout period consisting of standard SCS. In the trial treatment periods, patients were treated with HFSCS or sham stimulation. After 2 weeks of treatment, outcomes revealed that 42% of patients were responders in the high-frequency group vs 30% in the sham group. The mean benefit averaged over the 2 crossover sequences was 11%, favoring HFSCS (p=0.30). There were no differences between HFSCS and sham for VAS or health utility scores. However, there was a significant period effect: patients were more likely to respond in the first treatment.
period of the sequence regardless of sequence assignment. It is difficult to compare the Perruchoud et al (2013) findings with other RCTs due to a number of factors: (1) the enrollment population played a role (only people who had chronic pain despite previous use of standard SCS were able to participate); (2) the treatment period was short at only 2 weeks; (3) there was the period effect (patients tended to report greater pain reduction in the first period regardless of assigned sequence); and (4) the use of standard SCS during the 2 weeks preceded each treatment period, which led to carryover effects.

Kapural et al (2015, 2016)\textsuperscript{18,36} included patients with chronic leg and back pain who had received conventional medical management but not SCS. Kapural et al (2015) included an active but unblinded comparator (standard SCS) and included a trial SCS period up to 2 weeks post randomization after which only responders continued with stimulation. Outcomes were reported after 3, 12, and 24 months of treatment. The response in the standard SCS group was similar to previous trials of SCS, between 45\% and 50\% for back pain and 50\% to 55\% for leg pain at 3, 12, and 24 months. The response was clinically and statistically significantly higher with HFSCS than with SCS for both back (range, »75\% to 85\%) and leg pain (range, »70\% to 85\%) at all time points. A limitation of the Kapural et al (2015, 2016) trial was that nonresponders during the stimulation trial period were excluded from statistical analysis. Instead, assuming patients who were not implanted were nonresponders corresponds to response rates at 3 months of about 75\% in HFSCS and 37\% in SCS for back pain and 74\% and 46\% for leg pain (calculated, data not shown).

De Andres et al (2017) included adults from a single-center in Spain with FBSS refractory to standard treatment for at least 6 months with a pain intensity score of at least 5 out of 10 of a numeric rating scale (NRS).\textsuperscript{37} The comparator was SCS, and the trial was described as blinded but the method of blinding participants was not given. Patients were told that the two treatments were "equally effective." Outcome assessors were reportedly blinded although many of the assessments used were patient-reported. Outcomes were reported at 3, 6, and 12 months. The primary outcome was "a reduction of at least 50\% in pain intensity in the NRS score in the 12-month evaluation"; however, analysis of this outcome was not reported in the tables or text. The sample size calculations were unclear. Seventy-eight participants were assessed for eligibility, and 60 were randomized. It is unclear how many of the 18 not randomized were ineligible due to lack of response during the trial SCS period. Of the 60 randomized, 55 were included in the analysis. Although pain ratings improved in both groups, there were no statistically significant differences in change in NRS or ODI scores from baseline at any of the follow-up visits between groups. Lead migration during follow-up was similar in both groups. No patients developed an infection at the implant site. Because of poor reporting, this trial is difficult to evaluate.
<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Interventions</th>
<th>N at Baseline and Follow-Up</th>
<th>Results</th>
<th>Complications</th>
</tr>
</thead>
</table>
| Perruchoud et al (2013)\(^{30}\) | Chronic low back pain radiating in 1 or both legs; previously treated with SCS | • HFSCS  
• Sham  
2×2 crossover design with conventional SCS before both arms | N=40  
n=33            | 2 wk (HFSCS vs sham)  
• Responder (at least minimal improvement on patient-reported global impression of change) | One patient had malaise attributed to a vasovagal attack |
| Kapural et al (2015, 2016)\(^{18,36}\) | Chronic back and leg pain | • HFSCS  
• SCS | N=198  
n at 3 mo=171  
n at 24 mo=156 | 3 mo (HFSCS vs SCS)  
• Responder (≥50% back pain reduction with no stimulation-related neurologic deficit):  
  o Back pain  
  o Leg pain | Stimulation discomfort, 0% vs 47%  
No stimulated-rated SAEs or neurologic deficits |
| De Andes et al (2017)\(^{37}\) | FBSS | • HFSCS  
• SCS | N=60  
n=55 analyzed | 12 mo (HFSCS vs SCS)  
• Responders  
  o Back pain  
  o Leg pain | 77%49%<0.001  
73%49%<0.001 |
Case Series

Because RCT data are available for HFSCS, case series are discussed if they add information not available from the RCTs (e.g., longer follow-up, data on an important subgroup).

Al-Kaisy et al (2017) reported 36-month results for 20 patients with chronic low back pain without previous spinal surgery who were treated with 10-kHz HFSCS.38, 39 Seventeen patients completed the 36-month follow-up; 1 patient died (unrelated to study treatment), 1 patient was explanted due to lack of efficacy, and 1 patient had new leg pain. Among patients analyzed, the mean VAS score for pain intensity decreased from 79 to 10 mm (p<0.001) and the mean ODI score decreased from 53 to 20 (p<0.001). At baseline, 90% of the patients were using opioids compared with 12% at 36 months.

Section Summary: HFSCS for Chronic Trunk or Limb Pain

The evidence for HFSCS compared with standard SCS consists of an RCT that randomized 198 patients not previously treated with SCS and reported a clinically and statistically significant benefit associated with HFSCS. The crossover RCT enrolling patients with pain despite previous treatment with SCS reported no difference between HFSCS and sham stimulation. However, interpretation of this trial is limited due to the significant period effect.

SCS With Burst Stimulation (High Frequency)

In 2016, a supplement to an SCS device (in the form of a clinician programmer application), which allows for the provision of burst stimulation, was approved by the Food and Drug Administration. Studies that offer direct comparisons between standard SCS and burst SCS were sought to permit evaluation of the incremental benefit of burst SCS.

Systematic Reviews

Hou et al (2016) published a systematic review of burst SCS for the treatment of chronic back and limb pain.39 Reviewers identified five studies of burst SCS in patients with intractable chronic pain of more than three months in duration who had failed conservative treatment. Three studies, with sample sizes of 12, 15, and 20, respectively, used randomized crossover designs to compare burst stimulation...
with tonic stimulation; 2 studies also included a placebo stimulation intervention. Also, there were 2 case series with sample sizes of 22 and 48 patients, respectively. Data were collected after one to two weeks of treatment. Study findings were not pooled. Using American Academy of Neurology criteria, reviewers originally rated four studies as class III and 1 study as class IV. However, given the small sample sizes and short durations of follow-up of the four studies, all were downgraded to class IV. Overall, the level of confidence in the evidence on burst SCS for treating chronic pain without paresthesia was rated as "very low."

Randomized Controlled Trials
Five crossover RCTs with a total of 180 patients (range, 12-100 patients) were identified, 4 of which were conducted in Europe and the other in the U.S. (see Table 4). The trials by De Ridder et al (2010, 2013)\(^37,38\) enrolled patients with neuropathic pain, the trial by Schu et al (2014)\(^39\) enrolled patients with FBSS, Kriek et al (2017)\(^40\) enrolled patients with CRPS, and Deer et al (2018)\(^41\) enrolled patients with chronic intractable pain of the trunk and/or limbs. All trials compared burst stimulation with SCS. Schu et al (2014), De Ridder et al (2013), and Kriek et al (2017) also compared burst with a sham stimulation group. Schu et al (2014) included patients receiving standard SCS while De Ridder et al (2010, 2013) and Deer et al (2018) included patients not previously treated with SCS. It was not clear in Kriek et al (2017) whether patients had previously received SCS. Results were reported for 1 week of stimulation in Schu et al (2014) and De Ridder et al (2013), after two, 1-hour sessions of SCS or burst in De Ridder et al (2010), after 2 weeks of stimulation in Kriek et al (2017), and after 12 weeks of stimulation in Deer et al (2018). All trials reported reductions in absolute pain scores (NRS or VAS). Schu et al (2014) and De Ridder et al (2013) did not account for their crossover designs in data analyses, so analyses and p values are incorrect and not reported in Table 3. De Ridder et al (2010) did not provide between-group comparisons. Kriek et al (2017) reported only per-protocol analyses. Four trials reported numerically larger reductions in pain scores with burst than with SCS; Kriek et al (2017) did not report less pain for SCS at any frequency compared with burst. In Kriek et al (2017), 48% of patients preferred the 40-Hz SCS compared with 21%, 14%, 14%, and 3% that preferred 500-Hz SCS, 1200-Hz SCS, and burst and sham, respectively. The interpretation of four of the trials was limited by small sample sizes, short follow-up, and incorrect, inadequate, or missing statistical analyses.

The largest trial of burst stimulation is the Success Using Neuromodulation with BURST trial reported by Deer et al (2018).\(^40\) Success Using Neuromodulation with BURST was a 12-week, multicenter, randomized, unblinded, crossover, noninferiority trial evaluating traditional SCS or burst stimulation in 100 patients with chronic pain of the trunk and/or limbs enrolled between January 2014 and May 2015. Patients were SCS-naive and completed a trial stimulation period. Forty-five patients were randomized to SCS then burst, and the remaining 55 were randomized to burst then SCS. At the end of the second crossover period, patients were allowed to choose the stimulation mode they preferred and were followed for one year. Patients' mean age was 59 years; 60% of patients were women;
and 42% of patients had FBSS while 37% had radiculopathies. The primary outcome was the difference in mean VAS score, with a noninferiority margin of 7.5 mm. Analyses were intention-to-treat with missing values imputed using the hot deck method. Also, outcomes were imputed for patients who underwent invasive procedures for pain or had medication increases. The estimated difference in the overall VAS score between burst and SCS was -5.1 mm (95% upper confidence interval [CI], -1.14 mm), demonstrating noninferiority (p<0.001) and superiority (p<0.017). The proportion of patients with a decrease in VAS score of 30% or more was 60% (60/100) during burst stimulation and 51% (51/100) during SCS. The proportion of patients whose global impression was minimally improved, moderately improved, or very much improved was approximately 74% in both groups. There were no significant differences in Beck Depression Inventory scores (p=0.230). Patients were asked to rate their satisfaction levels for both periods: 78% were satisfied with both SCS and burst, 4% were dissatisfied with both SCS and burst, 7% were satisfied with SCS but not burst, and 10% were satisfied with burst but not SCS. However, more patients (70.8%) reported preferring burst stimulation over SCS stimulation after the 24-week crossover period. After 1 year of follow-up, 60 (68%) of the 88 patients completing follow-up reported preferring burst stimulation. The authors reported that the programming parameters were not standardized at the beginning of the study but a more standardized approach with lower amplitudes was implemented as the trial was ongoing. Trial limitations included the crossover design, which limits comparison of pain over longer periods of time, lack of blinding, and variable burst programming parameters.

Section Summary: SCS With Burst Stimulation for Chronic Trunk or Limb Pain

SCS with burst stimulation has been evaluated in five crossover RCTs. Four of the RCTs had fewer than 35 patients. Inferences drawn from these trials are limited by small sample sizes, short follow-up, and flawed statistical analyses. The largest RCT (Success Using Neuromodulation with BURST) was a 12-week, multicenter, randomized, unblinded, crossover, noninferiority trial assessing traditional SCS or burst stimulation in 100 patients with chronic pain of the trunk and/or limbs. The burst was noninferior to SCS for overall VAS score (at 12 weeks). The proportion of patients whose global impression was improved (minimally, moderately, or very much improved) was approximately 74% in both groups. Seventy-eight percent of patients reported being satisfied with both SCS and burst at the end of the 24-week crossover portion of the trial, while 7% were satisfied with SCS but not burst and 10% were satisfied with burst but not SCS. However, more patients (70.8%) reported preferring burst stimulation over SCS stimulation after the 24-week crossover.
<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Interventions</th>
<th>N at Baseline and FU</th>
<th>Results</th>
<th>Outcome Measure</th>
<th>Burst</th>
<th>SCS</th>
<th>Sham</th>
<th>Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>3×3 crossover design without washout</td>
<td>Schuet al (2014)</td>
<td>FBSS ▪ Burst stimulation ▪ SCS ▪ No stimulation (sham-control)</td>
<td>N=20 n=20</td>
<td>1 wk (burst vs SCS vs sham)</td>
<td>Mean NRS pain intensity scores, favoring burst</td>
<td>4.7</td>
<td>7.1</td>
<td>8.3</td>
<td>No SAEs reported</td>
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<td></td>
<td>Mean SF-MPQ pain quality scores, favoring burst</td>
<td>19.5</td>
<td>28.6</td>
<td>33.5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>DeRidder et al(2013)</td>
<td>Neuropathic limb pain ▪ Burst stimulation ▪ SCS ▪ No stimulation (sham-control)</td>
<td>N=15 n=15</td>
<td>1 wk (burst vs SCS vs sham)</td>
<td>Mean ODI scores, favoring burst</td>
<td>19.8</td>
<td>24.6</td>
<td>29.5</td>
<td>Not reported</td>
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<td></td>
<td>Mean improvement in VAS scores</td>
<td>3.8</td>
<td>2.2</td>
<td>1.4</td>
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<tr>
<td>2×2 crossover</td>
<td>DeRidder et al(2010)</td>
<td>Neuropathic pain ▪ Burst stimulation ▪ SCS</td>
<td>N=12 n=unclear</td>
<td>Two 1-h sessions (burst vs SCS)</td>
<td>Mean improvement in VAS scores</td>
<td>5.3</td>
<td>1.8</td>
<td></td>
<td>Not reported</td>
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<td>o Axial pain</td>
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<td></td>
<td>o Limb pain</td>
<td>7.3</td>
<td>4.4</td>
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<tr>
<td></td>
<td>Deer et al(2018)</td>
<td>Chronic intractable pain of the trunk and/or limbs ▪ Burst stimulation ▪ SCS</td>
<td>N=100</td>
<td>12 wk (burst vs SCS)</td>
<td>Mean improvement in SF-MPQ sensory scores</td>
<td>16.7</td>
<td>8.6</td>
<td></td>
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<td></td>
<td>Mean improvement in SF-MPQ affective scores</td>
<td>6.7</td>
<td>4.3</td>
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</tbody>
</table>

2 study-related SAEs (persistent pain and/or numbness and 1 unsuccessful lead placement); 21
Mean VAS scores at end of period, favoring burst
Diff = -5.1 mm (noninferiority type < 0.001)

Responder (≥30% improvement in VAS score)
60% 51%

5x5 crossover

Krief et al (2017)
CRPS
- Burst stimulation
- SCS 40 Hz
- SCS 500 Hz
- SCS 1200 Hz
- No stimulation (sham-control)
N=33 n=29
2 wk (burst vs SCS at 40, 500, and 1200 Hz vs sham)
No SAEs reported; 3 electrodes became dislodged; 2 patients reported itching

- Mean VAS scores at end of period
48 40\(^c\) 64
- Mean global perceived effect (7-point scale where 7 [very satisfied] to 1 [not at all satisfied])
4.7 5.3\(^c\) 3.5

CRPS: complex regional pain syndrome; Diff: difference; FBSS: failed back surgery syndrome; FU: follow-up; NRS: numeric rating scale; ODI: Oswestry Disability Index; SAE: serious adverse events; SCS: spinal cord stimulation; SF-MPQ: Short-Form McGill Pain Questionnaire; VAS: visual analog scale; RCT: randomized controlled trial.

\(^a\) Analyses do not appear to take into account properly the crossover design; therefore, p values are not reported here.

\(^b\) Statistical treatment comparisons not provided.

\(^c\) Results from SCS 40 Hz reported here. Three different levels of SCS were given. Similar results were reported for the other 2 SCS levels and are not shown in this table.

**DRG Neurostimulators for Chronic Trunk or Limb Pain**
Studies offering direct comparisons between standard SCS and DRG neurostimulators were sought to evaluate the benefits of SCS.

**DRG Implanted Device**

**Systematic Reviews**
Chang Chien et al (2017) published a systematic review on intraspinal stimulation of nondorsal column targets, including neurostimulation of the DRG for chronic pain. Reviewers included reports published through March 2015. They identified six studies of DRG stimulation: one conference presentation of the preliminary RCT data from A Safety and Effectiveness Trial of Spinal Cord Stimulation of the Dorsal Root Ganglion for Chronic Lower Limb Pain (ACCURATE, discussed below), four publications describing three prospective observational studies,
and one retrospective chart review. In the 3 prospective observational studies (n=32, 10, and 8), follow-up ranged from 7 days to 12 months. The retrospective study reported on 25 patients with a follow-up to 32 weeks. Meta-analyses could not be conducted with one RCT.

Vuka et al (2019) conducted a systematic review of the use of DRG stimulation for various pain syndromes (for example, CRPS, diabetic and non-diabetic peripheral neuropathy). The literature search, conducted through September 2018, identified 29 studies for inclusion, 1 RCT, (ACCURATE trial, discussed below) and the remaining were case series or case reports. The median sample size was 6 (range 1 to 152). Most of the studies reported positive results with DRG stimulation. No meta-analyses could be conducted.

**Randomized Controlled Trial**

The ACCURATE study (NCT01923285) compared DRG neurostimulation with standard SCS. As reported by Deer et al (2017), eligibility criteria for this multicenter unblinded noninferiority trial included chronic (≥6 months) intractable (failed ≥2 drugs from different classes) neuropathic pain of the lower limbs associated with a diagnosis of CRPS or causalgia and no previous neurostimulation. Patients were randomized to DRG stimulation with the Axium device or standard SCS. Patients first underwent a temporary trial of stimulation lasting 3 to 30 days, depending on the protocol at each site. Patients who had 50% or greater reduction in lower limb pain after the temporary trial were eligible for permanent stimulation. Those who failed temporary stimulation exited the trial but were included in the analysis as treatment failures. Trial characteristics are shown in Table 5.

A total of 152 patients were randomized, and 115 (n=61 DRG, n=54 SCS) had a successful temporary trial and continued to permanent implantation. The primary outcome was a composite measure of treatment success. Success was defined as: (1) 50% or greater reduction in VAS score and (2) no stimulation-related neurologic deficits. The noninferiority margin was set at 10%. Results are shown in Table 6. No patients experienced neurologic deficits in either group. Regarding paresthesias, at 3 months and 12 months, SCS patients were significantly more likely to report paresthesias in nonpainful areas than DRG patients. At 3 months, 84.7% of DRG patients and 65% of SCS patients reported paresthesias only in their painful areas; at 12 months, these percentages were 94.5% and 61.2%, respectively. Gaps in study relevance, design, and conduct are shown in Tables 7 and 8.

Mekhail et al (2019) conducted a sub-analysis on the patients receiving DRG neurostimulation in the ACCURATE study, to evaluate the occurrence and risk factors for paresthesia. Among the 61 patients with DRG implants, the rates of paresthesia at 1 month, 3 months, 6 months, 9 months, and 12 months were 84%, 84%, 66%, 62%, and 62%, respectively. The patients who were paresthesia-free reported similar or better outcomes for pain and QOL. Risk factors for paresthesia occurrence included higher stimulation amplitudes and frequencies, number of implanted leads, and younger age.
### Table 5. RCT Characteristics of DRG Implanted Devices

<table>
<thead>
<tr>
<th>Study</th>
<th>Countries</th>
<th>Sites</th>
<th>Dates</th>
<th>Participants</th>
<th>Interventions</th>
<th>SCS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deer et al (2017)⁴⁷, ACCURATE (NCT01923285)</td>
<td>U.S.</td>
<td>22</td>
<td>2013-2016</td>
<td>▪ CRPS or causal lower extremities &lt;br&gt;▪ Chronic pain (6 mo) &lt;br&gt;▪ Stimulation-naïve &lt;br&gt;▪ Failed ≥2pharmacologic treatments</td>
<td>AXIUM Neurostimulator System (n=76)</td>
<td>RestoreUltra and RestoreSensor (n=76)</td>
</tr>
</tbody>
</table>

CRPS: complex regional pain syndrome; DRG: dorsal root ganglion; SCS: spinal cord stimulation; RCT: randomized controlled trial.

### Table 6. RCT Results of DRG Implanted Devices

<table>
<thead>
<tr>
<th>Study</th>
<th>≥50% Reduction in VAS Scores for Pain</th>
<th>Physical Functioning</th>
<th>Emotional Functioning</th>
<th>Quality of Life</th>
<th>Safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deer et al (2017)⁴⁷. At 3 months</td>
<td></td>
<td>Mean BPI Interference</td>
<td>POMS Total Score</td>
<td>SF-36 PCS</td>
<td>SF-36 MCS</td>
</tr>
<tr>
<td>n</td>
<td>139</td>
<td>113</td>
<td>NR</td>
<td>113</td>
<td>113</td>
</tr>
<tr>
<td>DRG</td>
<td>81%</td>
<td>4.2</td>
<td>NR</td>
<td>11.8</td>
<td>8.3</td>
</tr>
<tr>
<td>SCS</td>
<td>56%</td>
<td>3.0</td>
<td>NR</td>
<td>9.4</td>
<td>4.8</td>
</tr>
<tr>
<td>TE (95% CI) (p)</td>
<td>NR (noninferiority p&lt;0.001; superiority p&lt;0.001)</td>
<td>1.1 (0.2 to 2.1) (&lt;0.05 favoring DRG)</td>
<td>NR (0.04 favoring DRG)</td>
<td>2.5 (-0.7 to 5.7)</td>
<td>3.5 (-0.5 to 7.5)</td>
</tr>
</tbody>
</table>

At 12 months
| n | 132 | 105 | NR | 105 | 105 | 152 |
| DRG | 74% | 3.9 | »18 | 11.5 | 6.2 | 11% |
| SCS | 53% | 2.6 | »8 | 8.0 | 3.6 | 15% |
| TE (95% CI) (p) | NR (noninferiority p<0.001; superiority p<0.001) | 1.3 (0.2 to 2.3) (<0.05 favoring DRG) | NR (<0.001) | 3.5 (-0.1 to 7.1) (0.04 favoring DRG) | 2.6 (-1.9 to 7.1) | NR (0.62) |

BPI: Brief Pain Inventory; CI: confidence interval; DRG: dorsal root ganglion; MCS: Mental Component Summary; NR: not reported; POMS: Profile of Mood States; PCS: Physical Component Summary; RCT: randomized controlled trial; SAE: serious adverse event; SCS: spinal cord stimulation; SF-36: 36-Item Short-Form Health Survey; TE: treatment effect; VAS: visual analog scale.

### Table 7. Relevance Gaps for RCTs of DRG Implanted Devices

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Outcomes</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deer et al (2017)⁴⁷</td>
<td>None noted</td>
<td>None noted</td>
<td>None noted</td>
<td>None noted</td>
<td>None noted</td>
</tr>
</tbody>
</table>

Key | 1. Intended use population unclear <br>2. Clinical context for treatment is unclear |

3. Study population unclear
4. Study population not representative of intended use
5. Study population is subpopulation of intended use

similar intensity as comparator
similar intensity as intervention
4. Not delivered effectively

4. Not established and validated measurements
5. Clinically significant difference not prespecified
6. Clinically significant difference not supported

sufficient duration for harms

Table 8. Study Design and Conduct Gaps for RCTs of DRG Implanted Devices

<table>
<thead>
<tr>
<th>Study</th>
<th>Allocation</th>
<th>Blinding</th>
<th>Selective Reporting</th>
<th>Follow-Up</th>
<th>Power</th>
<th>Statistical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deer et al (2017)47</td>
<td>None noted</td>
<td>1, 2. Patients and study staff not blinded. Outcomes mostly patient reported which could lead to bias. However, an active control (SCS) was used.</td>
<td>None noted</td>
<td>None noted</td>
<td>None noted</td>
<td>4. Treatment effects not reported for some outcomes but p values reported</td>
</tr>
</tbody>
</table>

Key
1. Participants not randomly allocated
2. Allocation not concealed
3. Allocation concealment unclear
4. Inadequate control for selection bias

1. Not blinded to treatment assignment
2. Not blinded outcome assessment
3. Outcome assessed by treating physician

1. Not registered
2. Evidence of selective reporting
3. Evidence of selective publication

1. High loss to follow-up or missing data
2. Inadequate handling of missing data
3. High number of crossovers
4. Inadequate handling of crossovers
5. Inappropriate exclusions
6. Not intent to treat analysis (per protocol for noninferiority trials)

1. Power calculations not reported
2. Power not calculated for primary outcome
3. Power not based on clinically important difference

1. Test is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event
2. Test is not appropriate for multiple observations per patient
3. Confidence intervals and/or p values not reported
4. Comparative treatment effects not calculated

DRG: dorsal root ganglion; RCT: randomized controlled trial; SCS: spinal cord stimulation.

Case Series
The remaining evidence for the use of DRG stimulation for chronic pain consists of case series.50,51,52,53,54,55,56,57
The case series evaluated the Axium DRG neurostimulator or an unnamed DRG stimulator in patients with FBSS, diabetic and non-diabetic peripheral nerve injury, postsurgical neuropathic pain, groin pain, and CRPS. Liem et al (2015) and Schu et al (2015). Liem et al (2015) had a larger sample size (N=51 vs N=29) and longer follow-up. Fifty-one patients with chronic pain of the trunk, lower back, or lower limbs who had failed conventional treatment underwent trial stimulation, and 32 underwent permanent implantation. Sample sizes ranged from 10 to 65 patients. One study had a six-month follow-up, most studies had one-year follow-up, and the largest study followed half of the patients for three years. For the studies reporting at least 1 year follow-up, the proportion of patients achieving a 50% or greater reduction in overall pain ranged from 49% to 83%. The largest case series, by Morgalla et al (2018), reported that after 3 years of follow-up, the patients continued to experience decreased Beck Depression Inventory scores, decreased Pain Disability Index scores, and 72% achieved a 50% or greater reduction in overall pain.

Deer et al (2019) compared the safety and complaint records from the manufacturers of DRG neurostimulation (n=500+) and SCS (n=2000+) devices, from April 2016 through March 2018. The overall safety event rate for the study timeframe was 3.2% for DRG systems and 3.1% for SCS systems. Persistent pain was reported at a rate of 0.2% by patients with DRG implants and 0.6% by patients with SCS implants. Infection rates were 1.1% in both groups of patients. Cerebrospinal leaks were reported in 0.5% of patients with DRG implants and in 0.3% of patients with SCS implants.

**DRG Wireless Injectable Device**

No controlled studies were identified. A case series, which included 11 patients, was published by Weiner et al (2016). This study included patients with FBSS who had chronic intractable neuropathic pain of the trunk and/or lower limbs. Five patients participated in phase 1 of the study (device not anchored), and six additional patients participated in phase 2 (device anchored). During phase 1, the device migrated more than was recommended and thus it was anchored in the remaining patients. Baseline VAS scores were five or higher in all patients. Seven (63%) of the 11 patients reported good to excellent overall pain relief (VAS score reduction, ≥50%), 2 patients reported fair overall intensity pain relief (25%-50% reduction), and 2 patients reported poor or no overall pain relief (0%-25%). No adverse events were reported.

**Section Summary: DRG Neurostimulators for Chronic Trunk or Limb Pain**

One unblinded RCT and many case series have evaluated DRG neurostimulators in patients with chronic trunk and/or limb pain. The RCT (n=152) found that patients receiving DRG neurostimulation had significantly higher rates of treatment success (physical functioning score and QOL measures) at 3 and 12 months compared with those receiving standard SCS devices. In addition, DRG neurostimulation was found to be noninferior to SCS in percentage achieving ≥50% pain reduction, emotional functioning score, and SF-36 scores. Both groups experienced paresthesias but patients in the DRG group reported less postural variation in paresthesia and reduced extraneous stimulation in nonpainful areas.
Patients in the DRG group also reported more improvement in interference with physical functioning and mood states. Rates of serious adverse events were similar. Many case series have also been published, all reporting results consistent with the RCT. The percentages of patients achieving 50% or greater reduction in overall pain ranged from 49% to 83% among the case series. The largest series, which had the longest follow-up of 3 years, reported that 83% of patients at 12 months and 72% of patients at 3 years experienced 50% or greater reduction in overall pain.

**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), amputation may be required. SCS has been investigated in this subset of patients as a technique to relieve pain and decrease the incidence of amputation.

An updated Cochrane review by Ubbink and Vermeulen (2013) assessed the use of SCS in peripheral vascular diseases. Reviewers included RCTs and non-RCTs evaluating the efficacy of SCS in adults with nonreconstructable, chronic critical leg ischemia. Six trials were identified; all were conducted in Europe and five were single-country studies. SCS was compared with other nonsurgical interventions. One study was not randomized, and none was blinded. In a pooled analysis of data from all 6 studies, there was a significantly higher rate of limb survival in the SCS group than in the control group at 12 months (pooled risk difference, -0.11; 95% 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 (95% CI, 5 to 50 patients). However, when the nonrandomized study was excluded, the difference in the rate of amputation no longer differed significantly between groups (risk difference, -0.09; 95% CI, -0.19 to 0.01). The SCS patients required significantly fewer analgesics, and more patients reached Fontaine stage II (intermittent claudication) than in the control group. There was no difference in ulcer healing (but only two studies were included in this analysis). In the 6 trials, 31 (15%) of 210 patients had a change in stimulation requiring intervention, 8 (4%) experienced the end of battery life, and 6 (3%) infections required device removal.

Previously, Klomp et al (2009) published a meta-analysis of RCTs that used SCS to treat patients with critical limb ischemia. The same five RCTs identified in the Cochrane review (previously described) were included. Reviewers did not find a statistically significant difference in the rate of amputation in the treatment or the control groups. The relative risk of amputation was 0.79, with a risk difference of -0.07 (p=0.15). Reviewers also conducted additional analyses of data from their 1999 RCT to identify factors associated with better or worse prognoses. They found that patients with ischemic skin lesions had a higher risk of amputation than patients with other risk factors. There were no significant interactions between this and any other prognostic factor. The analyses did not identify subgroups of patients who might benefit from SCS.
A systematic review of non-revascularization-based treatments by Abu Dabrh et al (2015) for patients with critical limb ischemia included SCS as one of the treatments. The review identified five RCTs for inclusion. In the pooled analysis, reviewers found that SCS was associated with reduced risk of amputation (odds ratio, 0.53; 95% CI, 0.36 to 0.79). However, they concluded that the evidence was of "relatively low quality ... mainly due to imprecision (ie, small sample size and wide CIs) and the risk of bias."

**Section Summary: Critical Limb Ischemia**
Five relatively small RCTs comparing SCS with usual care have assessed patients with critical limb ischemia. In some pooled analyses of these RCTs, SCS did not result in a significantly lower rate of amputation, although one meta-analysis which included a nonrandomized study reported a significant difference. This evidence is not sufficient to determine whether SCS would improve outcomes for patients with critical limb ischemia.

**Refractory Angina Pectoris**

**Systematic Reviews**
Several systematic reviews have evaluated SCS for treating angina pectoris. More recently, Pan et al (2017) identified 12 RCTs that evaluated SCS in patients with refractory angina pectoris. Most studies had small sample sizes (ie, <50 patients) and together totaled 476 patients. Reviewers did not discuss the control interventions reported in the RCTs. Pooled analyses favored the SCS group in most cases (eg, for exercise time after the intervention, pain level [VAS score], angina frequency) but there were not significant differences between intervention and control groups for physical limitation or angina stability.

Another systematic review was published by Tsigaridas et al (2015). It included nine RCTs evaluating SCS for refractory angina: seven compared SCS with low or no stimulation and two compared SCS with alternative medical or surgical therapy for angina. Reviewers found that most RCTs were small and variable in quality based on modified Jadad criteria. Reviewers reported: "two of the RCTs were of high quality (Jadad score 4); 2 were of low quality (Jadad score 1), and the remaining ones were of intermediate quality (Jadad score 2-3)." Most trials comparing SCS with low or no stimulation found improvements in outcomes with SCS; however, given limitations in the evidence base, reviewers concluded that larger multicenter RCTs would be needed to assess the efficacy of SCS for angina.

**Randomized Controlled Trials**
Zipes et al (2012) published an industry-sponsored, single-blind, multicenter trial with sites in the U. S. and Canada. This trial was terminated early because interim analysis by the data and safety monitoring board found the treatment futile. A total of 118 patients with severe angina, despite maximal medical treatment, were enrolled. Of the 118 patients, 71 (60%) underwent SCS implantation with the Intrel III neurostimulator (Medtronic). The remaining 47 patients did not meet eligibility criteria post enrollment or had other issues (eg, withdrew 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 of major adverse cardiac events, which included death from any cause, acute myocardial infarction, or revascularization through six months. Fifty-eight (85%) of 68 patients contributed data to the 6-month analysis; analysis was by intention-to-treat. The proportion of patients experiencing major adverse cardiac events at 6 months did not differ significantly between groups (12.6% in the high-stimulation group vs 14.6% in the low-stimulation group; p=0.81). The trial sample size was small, and it might have been underpowered for clinically meaningful differences.

A small controlled trial from Italy by Lanza et al (2011) randomized 25 patients to 1 of 3 treatment groups: SCS with standard stimulation (n=10), SCS with low-level stimulation (75%-80% of the sensory threshold) (n=7), or very low intensity SCS (n=8). Thus, patients in groups two and three 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 of 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 was 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 the use of nitroglycerin, QOL, VAS, Canadian Cardiovascular Society angina class, exercise-induced angina, and scores on five subscales of the Seattle Angina Questionnaire.

**Section Summary: Refractory Angina Pectoris**

Numerous small RCTs have evaluated SCS as a treatment for refractory angina. While some studies have reported benefit, most have not. In two more recent RCTs, there were no significant benefits for the primary outcomes. Overall, this evidence is mixed and insufficient to permit conclusions on whether health outcomes are improved.

**Heart Failure**

Findings of a small pilot crossover RCT evaluating SCS for heart failure were published by Torre-Amione et al (2014). 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 inability to walk more than 450 meters on a 6-minute walk test. All patients had an implanted heart device. Nine patients underwent SCS implantation and received three months of active and three months of inactive (off position) treatment, in random order. There was a one-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 one of the events in the composite endpoint. The events occurred in two patients while the
device was turned on and in two while it was turned off. One patient died about two months after implantation with the device turned off. The SCS devices did not interfere with the functioning of implantable cardioverter defibrillators.

Zipes et al (2016) reported on the results of Determining the Feasibility of Spinal Cord Neuromodulation for the Treatment of Chronic Heart Failure study, a prospective, multicenter, single-blind RCT comparing SCS using active stimulation with sham-control in patients who had New York Heart Association functional class III heart failure and a left ventricular ejection fraction of 35% or less. Sixty-six patients were implanted with an SCS and randomized 3:2 to SCS on (n=42) or SCS off (sham; n=24). For the trial's primary endpoint (change in left ventricular end systolic volume index from baseline to 6 months), there was no significant difference between groups (p=0.30). Other endpoints related to heart failure hospitalization and heart failure-related QOL scores and symptoms did not differ significantly between groups. After completion of the six-month randomization period, all subjects received active SCS stimulation. From baseline to 12-month follow-up, there were no significant treatment effects in the overall patient population for echocardiographic parameters (p=0.36). The trial was originally powered based on a planned enrollment of 195 implanted patients but enrollment was stopped early due to enrollment futility. The nonsignificant difference between groups might have been the result of underpowering. However, the absence of any treatment effects or between-group differences is further suggestive of a lack of efficacy of SCS for heart failure.

Section Summary: Heart Failure
Two RCTs have evaluated SCS as a treatment for heart failure. One was a small pilot crossover trial (n=9) that reported at least one adverse event in two patients with the device turned on and in two patients with the device turned off. The other RCT (n=66) was sham-controlled; it did not find significant differences between groups but might have been underpowered.

Cancer-Related Pain
A Cochrane review by Lihua et al (2013) assessed SCS for the treatment of cancer-related pain in adults. Reviewers did not identify any RCTs evaluating the efficacy of SCS in this population. Four case series using a before-after design (total n=92 patients) were identified. Peng et al (2015) updated this review, finding no new studies meeting inclusion criteria identified. They concluded: "Current evidence is insufficient to establish the role of SCS in treating refractory cancer-related pain."

Section Summary: Cancer-Related Pain
A Cochrane review did not identify any RCTs evaluating SCS for the treatment of cancer-related pain.

Potential Adverse Events
Whereas RCTs are useful for evaluating the efficacy, observational studies can provide data on the likelihood of potential complications. Mekhail et al (2011) retrospectively reviewed 707 patients treated with SCS between 2000 and
Patients' diagnoses included CRPS (n=345 [49%]), FBSS (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%]). Mean follow-up across studies was three years (range, three months to seven years). A total of 527 (36%) of the 707 patients eventually underwent permanent implantation of an SCS device. Hardware-related complications included lead migration in 119 (23%) of 527 patients, lead connection failure in 50 (9.5%) patients, and lead break in 33 (6%) patients. Revisions or replacements corrected the hardware problems. The authors noted that rates of hardware failure have decreased due to advances in SCS technology. Documented infection occurred in 32 (6%) of 527 patients with implants; there were 22 cases of deep infection, and 18 patients had abscesses. There was no significant difference in the infection rate by diagnosis. All cases of infection were managed by device removal.

Lanza et al (2012) reviewed observational studies on SCS in patients with refractory angina pectoris. They identified 16 studies (total n=1204 patients) but noted that patients might have been included in more than 1 report. The most frequently reported complications were lead issues (ie, electrode dislodgement or fracture requiring repositioning) or internal programmable generator failure during substitution. Lead issues were reported by 10 studies (n=450 patients). In these studies, 55 cases of lead or internal programmable generator failure were reported. No fatalities related to SCS treatment were reported.

Summary of Evidence

Treatment-Refractory Chronic Pain
For individuals who have treatment-refractory chronic pain of the trunk or limbs who receive standard SCS, the evidence includes systematic reviews and RCTs. The relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. Available RCTs are mixed regarding underlying diagnoses in select patient populations. However, those trials including patients with underlying neuropathic pain processes, have shown a significant benefit with SCS. Systematic reviews have supported the use of SCS to treat refractory trunk or limb pain, and patients who have failed all other treatment modalities have few options. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have treatment-refractory chronic pain of the trunk or limbs who receive HFSCS, the evidence includes three RCTs. The relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. One RCT comparing high-frequency with standard SCS in patients who had not previously been treated with SCS found a clinically and statistically significant benefit associated with HFSCS. Another RCT in patients who had chronic pain despite previous treatment with standard SCS found no benefit for those receiving high-frequency stimulation compared with sham-control; however, it is difficult to compare these findings with other trials of SCS due to the different patient populations, short treatment periods, and the crossover period effect. The
evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have treatment-refractory chronic pain of the trunk or limbs who receive DRG neurostimulation, the evidence includes an RCT and many case series. The relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. The unblinded RCT found that patients receiving DRG neurostimulation had significantly higher rates of treatment success (physical functioning score and QOL measures), at 3 and 12 months compared with those receiving standard SCS devices. DRG neurostimulation was found to be noninferior to SCS in percentage achieving >50% pain reduction, emotional functioning score, and SF-36 scores. Both groups experienced paresthesias but patients in the DRG group reported less postural variation in paresthesia and reduced extraneous stimulation in nonpainful areas. Rates of serious adverse events were similar between the two study arms. While most of the case series were small (sample sizes ranged from 10 to 65), all reported results that were consistent with the RCT results. The largest case series had the longest follow-up, reporting continued improvements in pain and psychological scores through three years. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

**Critical Limb Ischemia**

For individuals who have critical limb ischemia who receive SCS, the evidence includes several small RCTs. The relevant outcomes are overall survival, symptoms, functional outcomes, QOL, morbid events, hospitalizations, and treatment-related morbidity. In some pooled analyses of these RCTs, SCS did not result in a significantly lower rate of amputation, although one meta-analysis that included a nonrandomized study reported a significant difference. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Treatment-Refractory Angina Pectoris**

For individuals who have treatment-refractory angina pectoris who receive SCS, the evidence includes RCTs. The relevant outcomes are overall survival, symptoms, functional outcomes, QOL, morbid events, hospitalizations, and treatment-related morbidity. Numerous small RCTs have evaluated SCS as a treatment for refractory angina. While some have reported benefit, most have not. In two recent RCTs, there was no significant benefit in the primary outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Heart Failure**

For individuals who have heart failure who receive SCS, the evidence includes RCTs. The relevant outcomes are overall survival, symptoms, functional outcomes, QOL, morbid events, hospitalizations, and treatment-related morbidity. One small pilot crossover study (n=9) reported at least one adverse event in two patients with the device turned on and in two patients with the device turned off. A sham-controlled randomized trial (n=66) did not find significant differences between
groups but might have been underpowered to do so. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Cancer-Related Pain**
For individuals who have cancer-related pain who receive SCS, the evidence includes case series. The relevant outcomes are symptoms, functional outcomes, QOL, medication use, and treatment-related morbidity. No RCTs evaluating SCS in this population were identified. The evidence is insufficient to determine the effects of the technology on health outcomes.

**SUPPLEMENTAL INFORMATION**

**Practice Guidelines and Position Statements**

**International Association for the Study of Pain**
The International Association for the Study of Pain (2013) published recommendations on the management of neuropathic pain. The Association issued recommendations on spinal cord stimulation (SCS), considered weak due to the amount and consistency of the evidence. The recommendations supported the use of SCS for failed back surgery syndrome and complex regional pain syndrome (Table 9). In regards to high frequency stimulation and dorsal root ganglion stimulation, the publication states that long-term effectiveness of these techniques needs to be determined with further studies.

**Table 9. International Association for the Study of Pain Recommendations for SCS**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Comments</th>
<th>Quality of Evidence</th>
<th>Strength of Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRPS 1</td>
<td>Long-term benefits demonstrated, though benefits may diminish over time (in RCT, reoperation rate was 42%). May be considered for patients not responding to non-invasive treatments and sympathetic nerve blocks or for whom nerve blocks would be inappropriate.</td>
<td>Moderate</td>
<td>Weak</td>
</tr>
<tr>
<td>CRPS 2</td>
<td>Limited evidence</td>
<td>Low</td>
<td>Inconclusive</td>
</tr>
<tr>
<td>FBSS with radiculopathy</td>
<td>Based on 2 RCTs, appears to be better than reoperation and conventional medical management, however, response rates were relatively low and complication rates were relatively high.</td>
<td>Moderate</td>
<td>Weak</td>
</tr>
</tbody>
</table>

CRPS: complex regional pain syndrome; FBSS: failed back surgery syndrome; SCS: spinal cord stimulation; RCT: randomized controlled trial.

**American Society of Interventional Pain Physicians**
The American Society of Interventional Pain Physicians (2013) updated its evidence-based guidelines on interventional techniques for the management of chronic spinal pain. The guidelines included a statement that there is fair evidence for the following recommendation for SCS: "SCS is indicated in chronic low back pain with lower extremity pain secondary to FBSS, after exhausting multiple conservative and interventional modalities".
Earlier evidence-based guidelines from the Society (2007) 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.\textsuperscript{76} Reported complications with SCS ranged from infection, hematoma, nerve damage, lack of appropriate paresthesia coverage, paralysis, nerve injury, to death.

**American Society of Anesthesiologists**
The American Society of Anesthesiologists' Task Force and the American Society of Regional Anesthesia and Pain Management (2011) updated and published guidelines for chronic pain management.\textsuperscript{77} The guideline concluded that SCS "may be used in the multimodal treatment of persistent radicular pain in patients who have not responded to other therapies" and that SCS "may also be considered for other selected patients (e.g., CRPS, peripheral neuropathic pain, peripheral vascular disease, and postherpetic neuralgia.)"

**International Neuromodulation Society**
The International Neuromodulation Society convened a Neuromodulation Appropriateness Consensus Committee (NACC) to develop best practices for the use of dorsal root ganglion (DRG) stimulation for the treatment of chronic pain syndromes.\textsuperscript{78} The NACC was comprised of experts in anesthesiology, neurosurgery, and pain medicine. The NACC performed a systematic literature search through June 2017 and identified 29 publications providing evidence for the consensus recommendations. The evidence was graded using the modified Pain Physician criteria and the U.S. Preventive Services Task Force criteria. Table 10 summarizes the consensus recommendations on the use of DRG stimulation. Additional recommendations on the DRG stimulation procedure are provided in the publication.

**Table 10. NACC Consensus Recommendations for the Use of DRG Stimulation**

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Level</th>
<th>Grade</th>
<th>Consensus</th>
</tr>
</thead>
<tbody>
<tr>
<td>DRG stimulation should be considered primarily for patients with focal neuropathic pain syndromes with identified pathology</td>
<td>I</td>
<td>A</td>
<td>Strong</td>
</tr>
<tr>
<td>DRG stimulation is recommended for CRPS type I or type II of the lower extremity</td>
<td>I</td>
<td>A</td>
<td>Strong</td>
</tr>
<tr>
<td>DRG stimulation for CRPS type I or type II of the upper extremity requires more study</td>
<td>II-2</td>
<td>A</td>
<td>Strong</td>
</tr>
<tr>
<td>DRG stimulation for DPN may be effective based on limited data. Since there is good evidence for SCS, the use of DRG must be justified.</td>
<td>III</td>
<td>C</td>
<td>Strong</td>
</tr>
<tr>
<td>Evidence for DRG stimulation for non-diabetic peripheral neuropathy is limited; use should be determined on a case-by-case basis.</td>
<td>III</td>
<td>B</td>
<td>Moderate</td>
</tr>
<tr>
<td>Evidence for DRG stimulation for chronic postoperative surgical pain is limited; use should be determined on a case-by-case basis.</td>
<td>III</td>
<td>C</td>
<td>Moderate</td>
</tr>
<tr>
<td>DRG stimulation for pelvic pain should be used under strict criteria depending on mechanism of injury and visceral/somatic designation. Psychologic comorbidity is a contraindication.</td>
<td>III</td>
<td>I</td>
<td>Moderate</td>
</tr>
<tr>
<td>DRG stimulation for groin pain is recommended.</td>
<td>II-2</td>
<td>B</td>
<td>Strong</td>
</tr>
<tr>
<td>DRG stimulation is superior to standard SCS for unilateral focal pain from CRPS type I or type II of the lower extremity</td>
<td>I</td>
<td>A</td>
<td>Strong</td>
</tr>
</tbody>
</table>
No evidence for DRG stimulation over SCS for other indications

CRPS: complex regional pain syndrome; DPN: diabetic peripheral neuropathy; DRG: dorsal root ganglion; NACC: Neuromodulation Appropriateness Consensus Committee; SCS: spinal cord stimulation.

**National Institute for Health and Care Excellence**
The National Institute for Health and Care Excellence (2008) issued guidance on SCS for chronic pain of neuropathic or ischemic origin. The Institute recommended SCS as a treatment option for adults with chronic pain of neuropathic origin (measuring at least 50 mm on a 0-100 mm visual analog scale) that continues 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 the same guidance, the National Institute for Health and Care Excellence stated that SCS was not recommended for chronic pain of ischemic origin except in the context of research.

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

**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."  

**Ongoing and Unpublished Clinical Trials**
Some currently unpublished trials that might influence this review are listed in Table 11.
### Table 11. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02514590*</td>
<td>Wireless High Frequency Spinal Cord Stimulation for Chronic Pain</td>
<td>80</td>
<td>Feb 2019</td>
</tr>
<tr>
<td>NCT02902796</td>
<td>Comparison of 1000 Hertz (Hz), Burst, and Standard Spinal Cord Stimulation in Chronic Pain Relief</td>
<td>19</td>
<td>Dec 2019</td>
</tr>
<tr>
<td>NCT02093793*</td>
<td>A Randomized Controlled Study to Evaluate the Safety and Effectiveness of the Precision Spinal Cord Stimulator System Adapted for High-Rate Spinal Cord Stimulation</td>
<td>383</td>
<td>Nov 2019</td>
</tr>
<tr>
<td>NCT03014583</td>
<td>Study Comparing Conventional, Burst and High Frequency (HF) Spinal Cord Stimulation (SCS) in Refractory Failed Back Surgery Syndrome (FBSS) Patients After a 32-contact Surgical Lead Implantation (MULTIWAVE)</td>
<td>28</td>
<td>Jul 2020</td>
</tr>
<tr>
<td>NCT03318172</td>
<td>High-Density Spinal Cord Stimulation for the Treatment of Chronic Intractable Pain Patients: A Prospective Multicenter Randomized Controlled, Double-blind, Crossover Exploratory Study With 6-m Open Follow-up</td>
<td>100</td>
<td>Jul 2019</td>
</tr>
<tr>
<td>NCT03228420</td>
<td>A Post-Market, Multicenter, Prospective, Randomized Clinical Trial Comparing 10 kHz Spinal Cord Stimulation (HF10™ Therapy) Combined With Conventional Medical Management to Conventional Medical Management Alone in the Treatment of Chronic, Intractable, Neuropathic Limb Pain</td>
<td>360</td>
<td>Jul 2020</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02112474</td>
<td>The Pain Suppressive Effect of Alternative Spinal Cord Stimulation Frequencies</td>
<td>30</td>
<td>Nov 2016 (unknown)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

* Denotes industry-sponsored or cosponsored trial.

**REFERENCES**


**Billing Coding/Physician Documentation Information**

**63650**  Percutaneous implantation of neurostimulator electrode array, epidural

**63655**  Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural

**63661**  Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed

**63662**  Removal of spinal neurostimulator electrode plate/paddle(s) placed via
laminotomy or laminectomy, including fluoroscopy, when performed

63663  Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed

63664  Revision including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed

63685  Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling

63688  Revision or removal of implanted spinal neurostimulator pulse generator or receiver

95970  Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of waveform, 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

95971  Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of waveform, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (i.e., peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming

95972  Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of waveform, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour

L8679  Implantable neurostimulator, pulse generator, any type

L8680  Implantable neurostimulator electrode, each

L8685  Implantable neurostimulator pulse generator, single array, rechargeable, includes extension

L8686  Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension

L8687  Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension

L8688  Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

L8689  External recharging system for implanted neurostimulator, replacement only

C1767  Generator, neurostimulator (implantable), nonrechargeable

C1778  Lead, neurostimulator (implantable)

C1787  Patient programmer, neurostimulator
C1820 Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822 Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
C1883 Adaptor/extension, pacing lead or neurostimulator lead (implantable)
C1897 Lead, neurostimulator test kit (implantable)

ICD-10 Codes
G56.40- G56.43 Causalgia of upper limb code range
G57.70- G57.73 Causalgia of lower limb code range
G89.21- G89.29 Chronic pain, not elsewhere classified, code range
G89.4 Chronic pain syndrome
G90.50- G90.59 Complex regional pain syndrome I (CRPS I), code range
M25.50- M25.579 Pain in joint, code range
M54.10- M54.18 Radiculopathy, code range
M54.30- M54.32 Sciatica, code range
M54.40- M54.42 Lumbago with sciatica, code range
M54.5 Low back pain
M54.6 Pain in thoracic spine
M54.81 M54.89 Other dorsalgia codes
M54.89 Myalgia
M54.9 Dorsalgia, unspecified
M79.10- M79.18 Myalgia
M79.601- M79.676 Pain in limb, hand, foot, fingers and toes code range
R52 Pain, unspecified

CPT 95973 deleted 1/1/2016.

Additional Policy Key Words
N/A

Policy Implementation/Update Information
10/1/88 New policy added to the Surgery section titled Spinal Cord and Deep Brain Stimulation.
10/1/00 No policy statement changes.
10/1/01 No policy statement changes.
10/1/02 No policy statement changes.
10/1/03 No policy statement changes.
10/1/04 Policy statement revised to include “spinal cord stimulation is considered investigational as a treatment of critical limb ischemia as a technique to forestall amputation.”
10/1/05 Title changed to Spinal Cord Stimulation. Policy statement revised removing references to deep brain stimulation. Policy statement revised to remove the criteria “Patients are carefully screened, evaluated and diagnosed by multidisciplinary team prior to application of these therapies.” Policy statement revised to add the following criteria:
   ▪ 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 neurophy. Spinal cord stimulation is generally not effective in treating nociceptive pain (resulting from irritation, not damage to the nerves) and central deafferentation pain (related to CNS damage from a stroke or spinal cord injury).
   
No serious untreated drug habituation exists
10/1/06 No policy statement changes.
10/1/07 No policy statement changes.
10/1/08 No policy statement changes.
10/1/09 Policy statement revised to include use for refractory angina pectoris as investigational.
10/1/10 No policy statement changes.
10/1/11 No policy statement changes.
10/1/12 No policy statement changes.
10/1/13 No policy statement changes.
10/1/14 Investigational statement modified to state all other situations, with examples. Cancer-related pain added to investigational statement.
10/1/15 Heart failure added to investigational statement, and investigational statement edited for readability.
6/1/16 Investigational policy statement was added for high frequency spinal cord stimulation.
10/1/16 No policy statement changes.
6/1/17 Investigational statement added for wireless injectable dorsal root ganglion neurostimulation; high-frequency spinal cord stimulation added to medically necessary statement.
10/1/18 Policy statements unchanged. Policy Guidelines section revised to add Burst neurostimulation as an alternate programming of a standard SCS device.
6/1/19 The second policy statement was changed from investigational to medically necessary: "Dorsal root ganglion neurostimulation is considered medically necessary for the treatment of severe and chronic pain of the trunk or limbs."
10/1/19 No policy statement changes.
State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.