Spinal Cord Stimulation

Description
Spinal cord stimulation (SCS) delivers low-voltage electrical stimulation to the dorsal columns of the spinal cord to block the sensation of pain. SCS devices have a radiofrequency receiver that is surgically implanted and a power source (battery) that is either implanted or worn externally.

FDA REGULATORY STATUS
A large number of neurostimulator devices, some used for spinal cord stimulation (SCS), have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval (PMA) process. Examples of fully implantable SCS devices approved through the PMA process include the Cordis programmable neurostimulator (Cordis Corp., Downers Grove, IL), approved in 1981; the Itrel® (Medtronic, Minneapolis, MN), approved in 1984; the Genesis and Eon devices (St. Jude Medical) approved in 2001; and the Precision Spinal Cord Stimulator (Advanced Bionics, Switzerland), approved in 2004. FDA product code: LGW.
In May 2015, the Nevro Senza™ Spinal Cord Stimulator (Nevro Corp., Menlo Park, CA), a totally implantable neurostimulator device, was approved by FDA for the following indications: “chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome (FBSS), intractable low back pain, and leg pain.” This device uses a higher frequency of electrical stimulation (10 kHz) than standard devices.
Two wireless injectable neurostimulators have been approved or cleared by FDA. In February 2016, the Axium Neurostimulator System (Spinal Modulation, Menlo Park, CA) was approved by FDA through the PMA process. The device 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, Fort Lauderdale, FL) was cleared for marketing by FDA through the 510(k) process for treating chronic, intractable pain of the trunk and/or lower limbs.
In October 2016, FDA approved BurstDR™ stimulation (St. Jude Medical, Plano, TX), a clinician programmer application that provides intermittent “burst” stimulation for patients with certain St. Jude SCS devices.

POLICY STATEMENT
Spinal cord stimulation with standard or high-frequency stimulation may be considered medically necessary for 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.
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Wireless injectable dorsal root ganglion neurostimulation is **not medically necessary** for treatment of severe and chronic pain of the trunk or limbs.

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 of refractory angina pectoris, heart failure, and cancer-related pain.

**POLICY GUIDELINES**

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

**BENEFIT APPLICATION**

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

**RATIONALE**

**Summary of Evidence**

**Treatment-Refractory Chronic Pain**

For individuals who have treatment-refractory chronic pain of the trunk or limb who receive standard spinal cord stimulation (SCS), the evidence includes systematic reviews and randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Available RCTs are mixed in terms of the underlying diagnoses in select patient populations. However, those 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 highfrequency SCS, the evidence includes 2 RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. One RCT comparing high-frequency to standard SCS in patients who had not previously been treated with SCS found a clinically and statistically significant benefit associated with high-frequency SCS. The other RCT in patients who had chronic pain...
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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 to 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 wireless
injectable dorsal root ganglion neurostimulation, the evidence includes 1 RCT and case series. Relevant
outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related
morbidity. One unblinded RCT found that patients receiving wireless injectable stimulators had
significantly higher rates of treatment success at 3 and 12 months than those receiving standard SCS
devices. Both groups experienced paresthesias, so blinding would have been possible. Additional RCTs,
especially blinded with a sham-control group as well as an SCS control, are needed. The evidence is
insufficient to determine the effects of the technology on health outcomes.

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 1 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. The other RCT (N=66) was
sham controlled; it did not find significant differences between groups, but may 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements
European Academy of Neurology
In 2016, the European Academy of Neurology (EAN) published guidelines on neuromodulation in
management of chronic pain. These guidelines updated the 2007 the European Federation of

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supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or
pays for) this service or supply for a particular member.
Neurological Societies (EFNS) recommendations. For neuropathic pain and complex regional pain syndrome (CRPS), the quality of evidence and effect size were rated as "low" and tolerability/safety was rated as "moderate". EAN issued a "weak" recommendation for use of spinal cord stimulation (SCS) added to conventional medical management in CRPS, chronic back and leg pain, and painful diabetic neuropathy, and as an alternative to reoperation in postsurgical chronic back and leg pain.

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.”

REFERENCES
9. National Institute for Health and Clinical Excellence (NICE). Spinal cord stimulation for chronic pain of...

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**POLICY HISTORY**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>December 2011</td>
<td>New Policy</td>
<td></td>
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<tr>
<td>March 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature search. No change to policy statement.</td>
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<tr>
<td>March 2014</td>
<td>Update Policy</td>
<td>Policy updated with literature review. Added References 5, 14, 18, 19, 20 and 22. Investigational statement modified to state all other situations, with examples, adding cancer-related pain.</td>
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<tr>
<td>June 2016</td>
<td>Update Policy</td>
<td>Policy updated with literature review through February 19, 2016; references 1-3, 9, 12-13, 17, 19, 26, 28, 30, and 40 added. A not medically necessary policy statement added for high-frequency spinal cord stimulation.</td>
</tr>
<tr>
<td>June 2017</td>
<td>Revise Policy</td>
<td>Policy updated with literature review through February 23, 2017; references 13, 17, 19-25, 30, and 40 added. Rationale extensively revised. Not medically necessary statement added for wireless injectable dorsal root ganglion neurostimulation; high-frequency spinal cord stimulation added to medically necessary statement.</td>
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