Spinal Cord Stimulators

Policy # 00260
Original Effective Date: 08/18/2010
Current Effective Date: 06/01/2019

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

• Benefits are available in the member’s contract/certificate, and
• Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider stimulator trial to be eligible for coverage for the relief of chronic intractable neuropathic pain of the trunk and/or limbs for ANY of the following conditions when patient selection criteria are met:

• Lumbosacral arachnoiditis as documented by high levels of protein in the cerebrospinal fluid and/or imaging (MRI or myelography); or
• Nerve root injuries that are post-surgical or post-traumatic, including post-laminectomy syndrome (failed back syndrome); or
• Complex regional pain syndrome (CRPS), type I or type II (formerly known as reflex sympathetic dystrophy or causalgia); or
• Severe pain and disability with documented pathology or an objective basis for the pain.

Patient Selection Criteria
Coverage eligibility for spinal cord stimulation trial will be considered when all of the following criteria are met:

• Severe pain and disability with documented pathology or an objective basis for the pain (see Policy Guidelines); and
• Dorsal column stimulation is being used as a late or last resort after documented failure of at least six (6) consecutive months of physician-supervised conservative management (see Policy Guidelines); and
• There is no evidence of existing untreated drug addiction; and
• The patient has been evaluated by a pain management specialist prior to implantation; and
• All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment training, and follow-up of the patient must be available; and
• At least one surgical opinion has been obtained to ensure that the patient does not have a surgically correctable lesion; and
• Documentation of an evaluation by a mental health provider (e.g., a face-to-face assessment with or without psychological questionnaires and/or psychological testing) that confirms no evidence of an inadequately controlled mental health problem (e.g., alcohol or drug dependence, depression,

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psychosis) that would negatively impact the success of a spinal cord stimulator or contraindicate its placement.

Based on review of available data, the Company may consider stimulator implantation (permanent) to be eligible for coverage when all of the following criteria are met:

- The patient meets all of the criteria noted above for a stimulator trial; and
- A stimulator trial of at least three (3) days duration has been performed; and
- Documented pain reduction and functional improvement following the stimulator trial with at least a 50% reduction of target pain or analgesic medication use, and specific evidence of improved function.

Based on review of available data, the Company may consider stimulator revision or removal when ANY of the following criteria are met:

- Stimulator hardware complication including
  - Lead migration
  - Infection
  - Painful generator site
- Stimulator response complication including
  - Loss of effectiveness
  - Patient intolerance
  - Development of new neurologic deficits
- Planned procedure where stimulators are contraindicated including
  - Magnetic resonance imaging (MRI)
  - Automatic implantable cardioverter defibrillator (AICD)

**When Services Are Considered Not Medically Necessary**

Based on review of available data, the Company considers spinal cord stimulation for all other indications to be not medically necessary, including but not limited to the following to:

- Use of spinal cord stimulation for the treatment of critical limb ischemia to forestall amputation, refractory angina pectoris, heart failure, and cancer-related pain
- Dorsal root ganglion neurostimulation.

**Policy Guidelines**

Spinal cord stimulators, also known as dorsal column stimulators, are implantable devices used to treat chronic pain. Electrodes are surgically placed within the dura mater via laminectomy, or by percutaneous insertion into the epidural space. Low voltage electrical signals are delivered to the dorsal column of the spinal cord in order to override or mask sensations of pain.
The patient's pain distribution pattern determines the level at which the stimulation lead is placed. The lead may incorporate four (4) to eight (8) electrodes, with 8 electrodes typically used for complex pain patterns, such as bilateral pain or pain extending from the limbs to the trunk.

Implantation 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.

Extensive programming of the neurostimulators is often required to achieve optimal pain control.

Definitions

Conservative management should include a combination of strategies to reduce inflammation, alleviate pain, and improve function, including but not limited to the following:

- Prescription strength anti-inflammatory medications and analgesics
- Adjunctive medications such as nerve membrane stabilizers or muscle relaxants
- Physician-supervised therapeutic exercise program or physical therapy
- Manual therapy or spinal manipulation
- Alternative therapies such as acupuncture
- Appropriate management of underlying or associated cognitive, behavioral, or addiction disorders

Documentation of compliance with a plan of therapy that includes elements from these areas is required.

Reporting of symptom severity -- Severity of pain and its associated impact on activities of daily living (ADLs) and instrumental ADLs (IADLs) are key factors in determining the need for intervention. For purposes of this guideline, significant pain and functional impairment refers to pain that is at least 3 out of 10 in intensity, and is associated with inability to perform at least two (2) ADLs and/or IADLs.

Imaging studies -- All imaging must be performed and read by an independent radiologist. If discrepancies should arise in the interpretation of the imaging, the radiologist report will supersede. The results of all imaging studies should correlate with the clinical findings in support of the requested procedure.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
A large number of neurostimulator devices, some used for SCS, have been approved by the 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, and the Precision Spinal Cord Stimulator (Advanced Bionics, Switzerland), approved in 2004. FDA product code: LGW.
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In May 2015, FDA approved the Nevro Senza™ Spinal Cord Stimulator (Nevro Corp., Menlo Park, CA), a totally implantable neurostimulator device, 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, intractable low back pain, and leg pain.” This device uses a higher frequency of electrical stimulation (10 kHz) than standard devices.

In February 2016, the Axium Neurostimulator System (Spinal Modulation, Menlo Park, CA) was approved by FDA through the PMA process. This is an implanted device that stimulates the dorsal root ganglion. 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, Fort Lauderdale, FL), a wireless injectable stimulator, was cleared for marketing by FDA through the 510(k) process for treating chronic, intractable pain of the trunk and/or lower limbs. The Freedom device has implanted/injected microstimulators that contain electrode(s). The microstimulators with electrodes are powered through a wireless pack worn externally (external battery pack). 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, 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.

Centers for Medicare and Medicaid Services (CMS)
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.

**Rationale/Source**
**Summary of Evidence**

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**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. Relevant outcomes are symptoms, functional outcomes, quality of life, 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 high-frequency SCS, the evidence includes 3 RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, 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 case series. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. One unblinded RCT found that patients receiving DRG neurostimulation had significantly higher rates of treatment success at 3 and 12 months than those receiving standard SCS devices. 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 reduction in interference with physical functioning and mood states. Rates of serious adverse events were similar. Given that DRG neurostimulation targets a different portion of the sensory pathway and anatomic location than standard SCS, replication is needed in a confirmatory RCT. 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 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.

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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.

References

Policy History
Original Effective Date: 08/18/2010
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08/05/2010 Medical Policy Committee review
08/18/2010 Medical Policy Implementation Committee approval. New Policy.
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08/04/2011 Medical Policy Committee review
08/17/2011 Medical Policy Implementation Committee approval.
08/02/2012 Medical Policy Committee review
08/15/2012 Medical Policy Implementation Committee approval. Two additional criteria bullets added. Criteria changed to state that all of the criteria must be met instead of any of the criteria.
08/01/2013 Medical Policy Committee review
08/21/2013 Medical Policy Implementation Committee approval. No change to coverage.
08/07/2014 Medical Policy Committee review
08/20/2014 Medical Policy Implementation Committee approval. Added treatment of cancer-related pain as investigational.
12/03/2015 Medical Policy Committee review
12/16/2015 Medical Policy Implementation Committee approval. Added heart failure to investigational statement.
06/30/2016 Medical Policy Committee review
07/20/2016 Medical Policy Implementation Committee approval. New INV statement added for high-frequency spinal cord stimulation.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
07/06/2017 Medical Policy Committee review
07/19/2017 Medical Policy Implementation Committee approval. Removed wireless injectable dorsal from coverage statement. Rest of policy rewritten to track AIM.
07/05/2018 Medical Policy Committee review
07/11/2018 Medical Policy Implementation Committee approval. No change to coverage.
03/07/2019 Medical Policy Committee review

Next Scheduled Review Date: 03/2020

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Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

<table>
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<th>Code Type</th>
<th>Code</th>
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<tr>
<td>CPT</td>
<td>63650, 63655, 63663, 63664, 63685, 63688</td>
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<td>No codes</td>
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<tr>
<td>ICD-10 Diagnosis</td>
<td>All related diagnoses</td>
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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient’s illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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