Spinal Cord Stimulation

Policy # 00260
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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 spinal cord stimulation for the relief of chronic intractable neuropathic pain of the trunk and/or limbs to be **eligible for coverage** for the following conditions:

- 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).

Patient Selection Criteria
Coverage eligibility for spinal cord stimulation 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; 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; and
- Documentation of pain reduction and functional improvement following at least a three (3) day trial of percutaneous spinal stimulation. This should include at least a 50% reduction of target pain or analgesic medication use, and specific evidence of improved function; 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, psychosis) that would negatively impact the success of a spinal cord stimulator or contraindicate its placement.

When Services Are Considered Investigational
Note: Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers dorsal root ganglion (DRG) neurostimulation for treatment of severe and chronic pain of the trunk or limbs to be **investigational.***

Based on review of available data, the Company considers spinal cord stimulation for all other indications and when criteria are not met to be **investigational.***

Background/Overview

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 impact on activities of daily living (ADLs) is a key factor 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.

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.

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

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Dorsal Root Ganglion Neurostimulators for Chronic Trunk or Limb Pain

Studies that offer direct comparisons between standard SCS and DRG neurostimulators were sought to allow an evaluation of the incremental benefit of SCS.

DRG Implanted Device

Randomized Controlled Trial

One RCT, the ACCURATE study, compared DRG neurostimulation and standard SCS.27 The trial, published by Deer et al in 2016, was a multicenter unblinded noninferiority trial. Eligibility criteria 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 receive DRG stimulation with the Axium device or standard SCS. They 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. Implanted patients were followed for 12 months, with assessments at 3, 6, 9, and 12 months postimplant.

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. Twelve-month data were available for 105 patients (55 patients in the DRG group, 50 in the SCS group). The primary outcome was a composite measure of treatment

success. Success was defined as: (1) 50% or greater reduction in VAS score from baseline to the end of the trial phase; (2) VAS at 3 months that was 50% or greater lower than baseline; and (3) no stimulation-related neurologic deficits experienced during the study. The noninferiority margin was set at 10%; the trial was designed such that, if the noninferiority end point was met, a superiority analysis was also performed. Treatment success at 3 month was achieved by 55 (81.2%) of 69 patients in the DRG arm and 39 (55.7%) of 70 in the SCS arm. The noninferiority margin was met, and DRG was found to be statistically superior to SCS ($p<0.001$). At the 12-month follow-up, the primary end point was achieved by 49 (74.2%) of 66 in the DRG group and 35 (53%) of 66 in the SCS group and, again, DRG was considered noninferior to SCS and also superior ($p<0.001$). In terms of paresthesias, at 3 months and 12, 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. Twenty-one serious adverse events occurred in 19 patients (8 in the DRG group, 11 in the SCS group; difference between groups, p=*NS*). A limitation of the study was that it was unblinded and industry-sponsored, which could potentially bias outcome assessment and reporting.

Case Series
Two case series evaluating the Axium DRG neurostimulator were in patients with chronic trunk and/or limb pain were identified; these are Liem et al [2014], n=51 and Schu et al [2014], n=29. Liem et al had a larger sample size 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. From baseline to the 12-month follow-up, the mean VAS score decreased from 77.6 mm (n=32) to 33.6 mm (n=25; $p<0.001$). Sixty percent of patients achieved a 50% or greater reduction in overall pain.

DRG Wireless Injectable Device
No controlled studies were identified. A case series, which included 11 patients, was published by Weiner et al in 2016.. The 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 6 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 was ≥5 in all patients. Seven of the eleven patients (63%) reported good to excellent overall pain relief (≥50% reduction in VAS),

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 several case series 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 at 3 and 12 months than those receiving standard SCS devices. Both groups experienced paresthesias, so blinding would have been possible. Several case series have also been published. The largest series (N=32) with the longest follow-up found that 60% of patients had 50% or

greater reduction in overall pain at 12 months. Additional RCTs, especially blinded and with a sham-control group as well as an SCS control, are needed.

References

1. Centers for Medicare and Medicaid Services, National Coverage Determination for Electrical Nerve Stimulators, (1995) Baltimore MD, 3 pgs.
2. Chou R, Loeser JD, Owens DK, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. Spine. 2009;34(10):1066-77.
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6. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Spinal Cord Stimulation", 7.01.25, 7:2017.
7. AIM Specialty Health, AIM Musculoskeletal Program Guidelines for Interventional Pain Management, "Spinal Cord Stimulators for Permanent Implantation", November 1, 2017. Last Reviewed June 13, 2017.

Policy History

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08/05/2010	Medical Policy Committee review
08/18/2010	Medical Policy Implementation Committee approval. New Policy.
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.

Next Scheduled Review Date: 07/2019

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Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2017 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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

Code Type	Code
CPT	63650, 63655, 63663, 63664, 63685, 63688
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*****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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