Spinal Cord and Nerve Root Stimulators

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.*

Spinal Cord Stimulation (including burst, high frequency, and traditional stimulation methods)

Based on review of available data, the Company may consider stimulator trial to be **eligible for coverage**** when all of the following patient selection criteria are met:

- The patient has chronic intractable neuropathic pain of the trunk and/or limbs associated with at least ONE (1) of 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)
- 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 6 consecutive months of physician-supervised conservative management (See Policy Guideline Section); 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.

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

- The patient meets all of the criteria 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

Stimulator Revision or Removal
Based on review of available data, the Company may consider stimulator revision or removal to be **eligible for coverage**** when ANY of the following criteria are met:

- Stimulator hardware complication including
  - Lead migration
  - Infection
  - Painful generator site
- Stimulator response complications 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)

Dorsal Root Ganglion Stimulation
Based on review of available data, the Company may consider dorsal root ganglion (DRG) stimulation as an alternative to dorsal column stimulation in patients with moderate to severe chronic intractable pain of the lower limbs from complex regional pain syndrome (CRPS) types I or II and who otherwise meet above criteria for spinal cord stimulator trial or implantation to be **eligible for coverage.****

When Services Are Considered Not Medically Necessary

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

- 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 for any non-CRPS lower extremity indication
- Dorsal root ganglion neurostimulation in patients with CRPS lower extremity who currently have a spinal cord stimulator or who have previously failed spinal cord stimulation therapy
- Simultaneous placement of a dorsal column and dorsal root ganglion stimulator
- Replacement of a conventional spinal cord stimulator with a burst, high frequency, or DRG stimulator in the absence of an indication for stimulator removal

Policy Guidelines

Documentation supporting medical necessity should be submitted at the time of the request and must include the following components:
Conservative management should include a combination of strategies to reduce inflammation, alleviate pain, and improve function, including requirements for physical therapy AND at least one complementary conservative management strategy.

Physical therapy requirement includes ANY of the following:

- Physical therapy; or
- Physician or physical therapist-supervised home treatment program which includes flexibility and muscle strengthening exercises; or

- Exception to the physical therapy requirement in unusual circumstances (for instance, intractable pain so severe that physical therapy is not possible) when clearly documented in the medical record

Complementary conservative management requirement includes ANY of the following:

- Complementary alternative medicine including, but not limited to, chiropractic care, acupuncture, cognitive behavioral or massage therapy; or
- Anti-inflammatory medications and analgesics

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

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 refer 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 radiology report will supersede. The results of all imaging studies should correlate with the clinical findings in support of the requested procedure.

Background/Overview

Spinal cord stimulators, also known as dorsal column stimulators ("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 4 to 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 two-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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

A large number of neurostimulator devices, some used for spinal cord stimulation, have been approved by the FDA through the premarket approval processunder FDA product code: LGW (stimulator, spinal-cord, totally implanted for pain relief). 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 spinal cord stimulation devices.

The following table lists the original premarket approval information for devices with product code LGW.

Table 1. Premarket Approval Information for Devices With Product Code LGW

Device	Manufacturer	Original PMA number	Original approval date
Algovita Spinal Cord Stimulation System	Nuvectra Corporation	P130028	Nov 2015
Nevro Senza Spinal Cord Stimulation (SCS) System	Nevro Corporation	P130022	May 2015
Precision Spinal Cord Stimulation(SCS) System	Boston Scientific Corporation	P030017	Apr 2004
Genesis And Eon Family Neurostimulation (Ipg) Syst.	St. Jude Medical / Abbott Medical	P010032	Nov 2001
Itrel(R) Totally Implantable Spinal Cord Stim. Sys	Medtronic Neuromodulation	P840001	Nov 1984

Cordis Programmable Neural Stimulator Models 900a,	Cordis Corporation	P800040	Apr 1981

LGW: U.S. FDA product code; PMA: premarket approval.

In February 2016, the Axium Neurostimulator System (Abbott) was approved by the FDA through the premarket approval process (P150004) with product code PMP (Dorsal Root Ganglion Stimulator For Pain Relief). This implanted device stimulates the dorsal root ganglion. 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 (K180981) 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. FDA product code: GZB (Stimulator, Spinal-Cord, Implanted (Pain Relief))

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

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.

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

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4. COST B13 Working Group on Guidelines for Chronic Low Back Pain, Airaksinen O, Brox JI, et al. Chapter 4. European guidelines for the management of chronic nonspecific low back pain. Eur Spine J. 2006;15 Suppl 2:S192-300.
5. Lewis RAW, N. H.; Sutton, A. J., et al. . Comparative clinical effectiveness of management strategies for sciatica: systematic review and network meta-analyses. Spine J. 2015;15(6):1461-77.
6. Manchikanti L, Abdi S, Atluri S, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. Pain physician. 2013;16(2 Suppl):S49-283.

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.
08/04/2011 Medical Policy Committee review
08/17/2011 Medical Policy Implementation Committee approval.
08/02/2012 Medical Policy Committee review

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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
03/20/2019	Medical Policy Implementation Committee approval. Reporting of symptom severity: expanded to include IADLs as functional impairment. Added criteria for revision/removal of spinal cord stimulator. Separated criteria of trial stimulation and permanent stimulator implantation. Added exclusion of dorsal root ganglion stimulation.
03/05/2020	Medical Policy Committee review
03/11/2020	Medical Policy Implementation Committee approval. Severe pain and disability with documented pathology or an objective basis for the pain was removed as a bullet point from criteria.
05/07/2020	Medical Policy Committee review
05/13/2020	Medical Policy Implementation Committee approval. Added physical therapy or home therapy and one complementary modality to conservative management requirements, aligns with spine surgery guidelines. New indication for dorsal root

ganglion stimulation. Clarified exclusions for spinal cord and dorsal root ganglion stimulation. Title changed.
05/06/2021 Medical Policy Committee review
05/12/2021 Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled Review Date: 05/2022

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 2020 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	C1767, C1820, C1822, L8679, L8680, L8682, L8683, L8685, L8686,

	L8687, L8688
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. Food and Drug Administration (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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.