Spinal Cord and Dorsal Root Ganglion Stimulators

Policy # 00260
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Applies to all products administered or underwritten by B lue 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 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 after a spine surgery (e.g., failed back surgery syndrome [FBSS]); or
    - Complex regional pain syndrome (CRPS), type I or type II (formerly known as reflex sympathetic dystrophy or causalgia) which meets diagnostic criteria for CRPS (as per Budapest criteria, see Policy Guidelines) as outlined in Regional Sympathetic Nerve Blocks outlined in Policy Guideline Section; and
    - Peripheral diabetic neuropathy (PDN) when ALL of the following criteria are met:
        - Evidence of painful PDN of at least 12 months; and
        - Lower limb pain intensity of ≥ 5 on the VAS scale; and
        - Objective evidence for presence of neuropathy and severity: moderate-severe neuropathy on EMG/NCS (electromyography/nerve conduction studies); and
        - Confirmation of PDN diagnosis by at least one other specialist (e.g., neurologist); and

- BMI ≤ 35; and
- HbA1c ≤ 10%; and
- Daily morphine equivalents of 120 mg or less; and
- Documented medical clearance as candidate for the procedure; and
- Other causes of neuropathy have been ruled out; and
- Optimization of medical management (i.e., diabetes, inflammatory/infectious, vitamin/nutritional deficiencies, renal failure, possible Rx drug/iatrogenic, exposure to toxins); and
- Failed trial (or documented intolerance) to multiple pharmacologic agents in at least 2 categories (i.e., antidepressants like duloxetine [Cymbalta], anticonvulsants like gabapentin/pregabalin, topicals like capsaicin, etc.); and
- Absence of upper limb pain intensity of ≥ 3 on a VAS scale

- 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 multimodal conservative management (See Policy Guideline Section); and
- Failed trial of regional sympathetic blocks in the case of CRPS; 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 (excludes CRPS and PDN); and
- Documentation of an evaluation by a licensed mental health provider within 6 months of a stimulator trial request (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.

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Note:
Spinal cord stimulator trial must be performed with percutaneously placed leads except under certain situations (e.g., a prior fusion or narrow spinal canal complicates a percutaneous lead 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 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 may be contraindicated including:
  - Magnetic resonance imaging (MRI) when other indicated tests have been shown to be inconclusive (such as a CT-myelogram, EMG/NCS, plain x-rays with multiple views)
  - 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 functioning 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 (SCS) with a burst, high frequency, closed-loop system (e.g., Evoke™ SCS system)‡, or DRG stimulator in the absence of an indication for stimulator removal or when the current permanent SCS failed to provide adequate pain relief.

Based on review of available data, the Company considers a repeat trial of spinal cord stimulation to be **not medically necessary**** in the following situations:

- If the initial trial was successful; or
- If the initial trial failed, unless failure was due to inability to guide the percutaneous stimulator lead to the appropriate level secondary to anatomical abnormalities. In such cases a surgically placed paddle lead may be appropriate**.**

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 correct underlying dysfunction, including physical therapy AND at least one complementary conservative treatment-strategy.

- Physical therapy requirement includes ANY of the following:
    - Physical therapy rendered by a qualified provider of physical therapy services; or
        - Supervised home treatment program that includes all of the following: Participation in a patient specific or tailored program
        - Initial active instruction by MD/DO/PT with redemonstration of patient ability to perform exercises
        - Compliance (documented or by clinician attestation on follow-up evaluation)
    - 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 treatment requirement includes ANY of the following:
    - Anti-inflammatory medications and analgesics (in the absence of contraindications)
    - Adjunctive medications such as nerve membrane stabilizers or muscle relaxants (in the absence of contraindications)
    - Alternative therapies such as acupuncture, chiropractic manipulation, massage therapy, activity modification, and/or a trial period of rest (e.g., from the aggravating/contributing factors) where applicable
- Interventional modalities
    - Minimally invasive interventional pain procedures such as epidural injections, facet joint procedures, and sympathetic blocks as appropriate

Clinical reevaluation. In most cases, reevaluation should include a physical examination. Direct contact by other methods, such as telephone communication or electronic messaging, may substitute for in-person evaluation when circumstances preclude an office visit.

Failure of conservative management requires **ALL** of the following:

- Patient has completed a full course of conservative management (as defined above) for the current episode of care; and
- Worsening of or no significant improvement in signs and/or symptoms upon clinical reevaluation; and
- More invasive forms of therapy are being considered.

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.

The Budapest Criteria for complex regional pain syndrome (CRPS) include:

- Continuing pain that is disproportionate to any inciting event
- At least ONE symptom reported in at least THREE (3) of the following categories:
    - Sensory: Hyperesthesia or allodynia
    - Vasomotor: Temperature asymmetry, skin color changes, skin color asymmetry
    - Sudomotor/edema: Edema, sweating changes, or sweating asymmetry
    - Motor/trophic: Decreased range of motion, motor dysfunction (e.g., weakness, tremor, dystonia), ortrophic changes (e.g., hair, nail, skin)
- At least ONE sign at time of evaluation in at least TWO (2) of the following categories:
    - Sensory: Evidence of hyperalgesia (to pinprick), allodynia (to light touch, temperature sensation, deepsomatic pressure, or joint movement)
    - Vasomotor: Evidence of temperature asymmetry (>1°C), skin color changes or asymmetry
    - Sudomotor/edema: Evidence of edema, sweating changes, or sweating asymmetry
    - Motor/trophic: Evidence of decreased range of motion, motor dysfunction (e.g., weakness, tremor,dystonia), or trophic changes (e.g., hair, nail, skin)
    - No other diagnosis better explaining the signs and symptoms

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Background/Overview

Chronic Pain
Spinal cord stimulation 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 (CPRS; ie, chronic reflex sympathetic dystrophy). There has also been interest in spinal cord stimulation 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
Spinal cord stimulation (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 spinal cord stimulation is uncertain, but may be related to either activation of an inhibitory system or blockage of facilitative circuits.

Spinal cord stimulation 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 4 to 8 electrodes, with 8 electrodes more commonly used for complex pain patterns. There are 2 basic types of power source: 1 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 8 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 spinal cord stimulation may require extensive programming of the neurostimulators to identify the optimal electrode combinations and stimulation channels.

Traditional spinal cord stimulation devices use electrical stimulation with a frequency of 100 to 1000 Hz. High frequency devices use electrical stimulation with a frequency of 10,000 Hz. In 2016, the

U.S. Food and Drug Administration (FDA) approved a clinician programmer application that allows a spinal cord stimulation 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 spinal cord stimulation 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. Other neurostimulators target the dorsal root ganglion.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

A large number of neurostimulator devices have been approved by the FDA through the premarket approval process under FDA product code: LGW (stimulator, spinal-cord, totally implanted for pain relief), PMP (Dorsal Root Ganglion Stimulator for Pain Relief), and GZB (Stimulator, Spinal-Cord, Implanted [Pain Relief]) (Table 1). 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.

Table 1. Premarket Approval Information for Spinal Cord and Dorsal Root Ganglion Stimulator Devices

Device	Manufacturer	Product code	Original approval date	Original PMA number	Indication
Algovita SCS System	Nuvectra Corporation	LGW	Nov 2015	P130028	Chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome, intractable low back pain, and leg pain.
Axium (1st generation) and Proclaim DRG	Abbott Medical	PMP	Feb 2016	P150004	Moderate to severe chronic intractable pain of the lower limbs in

(2nd generation) Neurostimulator System					adult patients with Types I and II CRPS
Cordis Programmable Neural Stimulator Models 900a	Cordis Corporation	LGW	Apr 1981[a]	P800040	Stimulator, Spinal-Cord, Totally Implanted For Pain Relief
Freedom SCS	Stimwave Technologies	GZB	Aug 2016	K180981	Chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain
Genesis And Eon Family Neurostimulation (Ipg) System; Eterna Spinal Cord Stimulation (SCS) System;Prodigy, Proclaim, and Proclaim XR Spinal Cord Stimulation (SCS) Systems	St. Jude Medical/ Abbott Medical	LGW; QRB	Nov 2001	P010032	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 and leg pain, and diabetic peripheral neuropathy of the lower extremities.
Restore, Itrel, Synergy, Intellis, And Vanta Spinal Cord Stimulation Systems	Medtronic Neuromodulation	LGW	Nov 1984	P840001	Chronic, intractable pain of the trunk and/or limbs-including unilateral or bilateral pain associated with the following conditions:

					• Failed Back Syndrome (FBS) or low back syndrome or failed back • Radicular pain syndrome or radiculopathies resulting in pain secondary to FBS or herniated disk • Postlaminectomy pain • Multiple back operations • Unsuccessful disk surgery • Refractory Degenerative Disk Disease (DDD)/herniated disk pain • Peripheral causalgia • Epidural fibrosis • Arachnoiditis or lumbar adhesive arachnoiditis • Complex Regional Pain Syndrome (CRPS), Reflex Sympathetic Dystrophy (RSD), or causalgia • Diabetic peripheral neuropathy of the lower extremities
Precision SCS Systems	Boston Scientific Corporation	LGW	Apr 2004	P030017	Chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated

					with failed back surgery syndrome, Types 1 and 2 CRPS, intractable low back pain and leg pain
Evoke SCS System	Saluda Medical Pty Ltd	LGW	Feb 2022	P190002	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.
Senza SCS Systems	Nevro Corporation	LGW	May 2015	P130022	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 When programmed to include a frequency of 10 kHz: Chronic intractable pain of the lower limbs, including unilateral or bilateral pain, associated with diabetic neuropathy; non-surgical refractory back pain (intractable back pain without prior

					surgery and not a candidate for back surgery)

CRPS:Complex regional pain syndrome; PMA: premarket approval; SCS: spinal cord stimulation.
[a] Withdrawn in 2016

In September 2020, the FDA released a letter to healthcare providers reminding them to conduct a trial stimulation period before implanting a spinal cord stimulator as the agency continues to receive reports of serious adverse effects associated with these devices. Between July 27, 2016 and July 27, 2020, the FDA received 107,728 medical device reports related to spinal cord simulators intended for pain including 497 associated with patient death, 77,937 with patient injury, and 29,924 with device malfunction. The most frequently reported patient problem codes were inadequate pain relief (28.1%), pain (15.2%), unexpected therapeutic effects (10.9%), infection (7.5%), and discomfort (5.9%). Additionally, the most frequently reported device problem codes were charging problems (11.2%), impedance (10.6%), migration (7.2%), battery problem (6.4%), and premature discharge of battery (4.2%). The FDA made the following recommendations for clinicians to consider:

- Conduct a trial stimulation as described in the device labeling to identify and confirm satisfactory pain relief before permanent implantation.
- Permanent spinal cord stimulation should only be implanted in patients who have undergone and passed a stimulation trial.
- Providers typically perform a stimulation trial on a patient for 3 to 7 days, and success is usually defined by a 50% reduction in pain symptoms. Inform patients about the risks of serious side effects and what to expect during the trial stimulation.
- Before implantation of any spinal cord stimulation, discuss the benefits and risks of the different types of implants and other treatment options, including magnetic resonance imaging compatibility of the devices.
- Before implantation, provide patients with the manufacturer's patient labeling and any other education materials for the device that will be implanted.
- Develop an individualized programming, treatment, and follow-up plan for spinal cord stimulation therapy delivery with each patient.
- Provide each patient with the name of the device manufacturer, model, and the unique device identifier of the implant received.

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. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Spinal cord stimulation 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 spinal cord stimulation 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 spinal cord stimulation, 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 heterogeneous regarding underlying diagnoses in select patient populations. However, the trials including patients with underlying neuropathic pain processes have shown a significant benefit with spinal cord stimulation. Systematic reviews have supported the use of spinal cord stimulation 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 an improvement in the net health outcome.

For individuals who have treatment-refractory chronic pain of the trunk or limbs who receive high-frequency spinal cord stimulation, the evidence includes a systematic review and 4 RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Two RCTs that enrolled participants not previously treated with spinal cord stimulation reported clinically and statistically significant benefits associated with high-frequency spinal cord stimulation. Another RCT in patients who had chronic pain despite previous treatment with standard spinal cord stimulation 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 spinal cord stimulation 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 an improvement in the net health outcome.

For individuals who have treatment-refractory chronic pain of the trunk or limbs who receive dorsal root ganglion neurostimulation, the evidence includes a systematic review, an RCT, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The unblinded RCT found that patients receiving dorsal root ganglion neurostimulation had significantly higher rates of treatment success (physical functioning score and quality of life measures), at 3 and 12 months compared with those receiving standard spinal cord stimulation devices. Dorsal root ganglion neurostimulation was found to be noninferior to spinal cord stimulation in the percentage achieving $\geq$50% pain reduction, emotional functioning score, and 36-Item Short-Form Health Survey scores. Both groups experienced paresthesias but patients in the dorsal root ganglion group reported less postural variation in paresthesia and reduced extraneous stimulation in nonpainful areas. Rates of serious adverse events were similar between the 2 study arms. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Critical Limb Ischemia
For individuals who have critical limb ischemia who receive spinal cord stimulation, the evidence includes systematic reviews of several small RCTs. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. In pooled analyses, spinal cord stimulation was associated with a lower risk of amputation versus control, but results were not consistently statistically significant due to differences in methodologies. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Treatment-Refractory Angina Pectoris
For individuals who have treatment-refractory angina pectoris who receive spinal cord stimulation, the evidence includes systematic reviews and RCTs. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. Numerous small RCTs have evaluated spinal cord stimulation as a treatment for refractory angina. While some have reported benefits, most have not. In 2 recent RCTs, there was no significant benefit in the primary outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Heart Failure
For individuals who have heart failure who receive spinal cord stimulation, the evidence includes RCTs. Relevant outcomes are overall survival, symptoms, functional outcomes, quality of life, morbid events, hospitalizations, and treatment-related morbidity. An RCT (N=66) comparing spinal cord stimulation 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 did not find significant differences between groups, but might have been underpowered to do so. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

Cancer-Related Pain
For individuals who have cancer-related pain who receive spinal cord stimulation, the evidence includes case series. Relevant outcomes are symptoms, functional outcomes, medication use, and treatment-related morbidity. No RCTs evaluating spinal cord stimulation in this population were identified. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

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Policy History

Original Effective Date: 08/18/2010
Current Effective Date: 04/14/2024

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.
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.
12/02/2021	Medical Policy Committee review
12/08/2021	Medical Policy Implementation Committee approval. Waived surgical opinion requirement for patients with CRPS. Updated references. Allowed minimally invasive pain procedures to satisfy conservative management definition, specified

	timing of mental health evaluation, defined indications for repeat stimulator trial. Updated to track AIM guidelines.
12/01/2022	Medical Policy Committee review
12/07/2022	Coding update
12/14/2022	Medical Policy Implementation Committee approval. More rigorous definition of the supervised home PT requirement and removal of CBT as a conservative care modality. A repeat trial is not medically necessary if the initial trial failed, unless failure was due to mechanical causes, such as device failure or failure to guide the percutaneous stimulator lead to the appropriate level.
12/07/2023	Medical Policy Committee review
12/13/2023	Medical Policy Implementation Committee approval. Addition of closed-loop system and clarifying edits made to both NMN statements.
03/07/2024	Medical Policy Committee review
03/13/2024	Medical Policy Implementation Committee approval. Spinal cord/Dorsal root stimulators: expanded stimulator trial criteria for PDN; added clarifications. Added references. Title changed from Spinal Cord and Nerve Root Stimulators to Spinal Cord and Dorsal Root Ganglion Stimulators.

Next Scheduled Review Date: 03/2025

Coding

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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, C1826, C1827, 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 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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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.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.