

Cigna Medical Coverage Policies – Musculoskeletal Spinal Cord and Dorsal Root Ganglion Stimulation

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Instructions for use

The following coverage policy applies to health benefit plans administered by Cigna. Coverage policies are intended to provide guidance in interpreting certain standard Cigna benefit plans and are used by medical directors and other health care professionals in making medical necessity and other coverage determinations. Please note the terms of a customer's particular benefit plan document may differ significantly from the standard benefit plans upon which these coverage policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a coverage policy.

In the event of a conflict, a customer's benefit plan document always supersedes the information in the coverage policy. In the absence of federal or state coverage mandates, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of:

1. The terms of the applicable benefit plan document in effect on the date of service
2. Any applicable laws and regulations
3. Any relevant collateral source materials including coverage policies
4. The specific facts of the particular situation

Coverage policies relate exclusively to the administration of health benefit plans. Coverage policies are not recommendations for treatment and should never be used as treatment guidelines.

This evidence-based medical coverage policy has been developed by eviCore, Inc. Some information in this coverage policy may not apply to all benefit plans administered by Cigna.

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CMM-211: Spinal Cord and Dorsal Root Ganglion Stimulation

Definitions

- **Spinal cord stimulation**, also known as dorsal column stimulation or neuromodulation, is a reversible therapy applied for neuropathic pain with techniques that include multi-output implanted pulse generators and a choice of electrodes, some of which can be placed percutaneously. The technical goal of this therapy is to achieve stimulation of paresthesia from the dorsal horn of the spinal cord at a subjectively comfortable level, overlapping an individual's topography of pain. The procedure initially involves a short-term trial (i.e., greater than 48 hours) of percutaneous (temporary) spinal cord stimulation, prior to the subcutaneous (permanent) implantation of the spinal cord stimulation device, to determine whether the spinal cord stimulator device will induce sufficient pain relief to render it medically necessary. Although it may vary depending on the specific device, a traditional dorsal column stimulator (i.e., non-high-frequency) generally produces a pulse width between 20-1000 μ s and frequencies between 2 and 1200 Hz. Some devices allow adjustment of the settings, including burst- and/or continuous-mode stimulation.
- **High-frequency spinal cord stimulation**, also referred to as kilohertz frequency spinal cord stimulation or HF10, is a type of spinal cord stimulation (SCS) providing a higher frequency than traditional spinal cord stimulator systems. The HF10 SCS uses low-amplitude, high-frequency, and short-duration pulses. HF10 SCS does not generate paresthesia and operates at a frequency of 10,000 Hz to provide pain relief in comparison to traditional spinal cord stimulation systems which operate at a lower frequency and do generate paresthesia. As an alternative to traditional dorsal spinal column stimulation HF10 SCS is proven safe and effective for treatment of chronic, intractable low back and leg pain in individuals with failed back surgery syndrome (FBSS).
- **Peripheral nerve stimulation**, in contrast to spinal cord stimulation, involves implantation of electrodes near or on a peripheral nerve to reduce pain. **Peripheral nerve field stimulation** is a technology that involves placement of electrodes subcutaneously within an area of maximal pain, with the objective of stimulating a region of affected nerves to reduce pain. Depending on the targeted nerve, leads may be placed percutaneously just under the skin or via an open approach for larger deeper peripheral nerves. Similar to spinal cord stimulation, a short-term trial is required prior to permanent implantation of a generator. The use of these technologies, used alone or in combination with spinal cord stimulation for treatment of pain conditions is under investigation.
 - ◆ **Please note:** this guideline does not apply to simple or complex brain or peripheral (i.e. cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter.

- **Dorsal root ganglion (DRG) stimulation** is an emerging method of treatment for neuropathic pain. With DRG stimulation leads are placed percutaneously into the epidural space under fluoroscopic guidance directly over the targeted dorsal root ganglion within the lumbar or sacral region of the spine. Similar to spinal cord stimulation, a short-term trial (i.e., greater than 48 hours) is recommended using an external pulse generator; upon success of the trial a permanent pulse generator may then be implanted. At this time, the evidence in the peer-reviewed scientific literature is insufficient to support long-term safety and efficacy. The use of this technology for treatment of pain conditions remains under investigation.
- **Failed back surgery syndrome (FBSS)** is lumbar spinal pain of unknown origin despite surgical intervention or appearing after surgical intervention for spinal pain originally in the same spinal region. Procedures/surgery that do not encroach into the spinal canal e.g. interspinous/interlaminar/facet distraction, kyphoplasty/vertebroplasty surgery, etc.
- **Critical limb ischemia (CLI)** describes a condition in which tissue perfusion is reduced such that spinal stimulators may be appropriate for the treatment of intractable rest pain secondary to chronic limb ischemia. Ischemic rest pain is pain that occurs in the toes or in the area of the metatarsal heads. Occasionally, it occurs in the foot proximal to the metatarsal heads. Elevation of the limb above or at the horizontal position aggravates the pain and pendency, to some degree at least, brings relief. The pain is secondary to severe arterial insufficiency resulting in inadequate perfusion to the distal lower extremity.

Indications

- The determination of medical necessity for implantation of a dorsal column spinal cord stimulator (SCS) is always made on a case-by-case basis.
- A dorsal column stimulator capable of **using either high-frequency or non-high-frequency stimulation** (dual-mode) is considered an equally effective alternative for the treatment of any of the medically necessary indications listed below, when the device uses non-high-frequency stimulation.
- A dorsal column stimulator **using high frequency** is considered an equally effective alternative to non-high-frequency stimulation **only** for the treatment of chronic intractable pain, secondary to failed back surgery syndrome (FBSS) as noted below.

Chronic Intractable Pain Secondary to Failed Back Surgery Syndrome (FBSS)

- A short-term trial (i.e., greater than 48 hours) spinal cord stimulation (i.e., non-high-frequency, high-frequency [HF10 SCS]), is considered **medically necessary** for the treatment of chronic intractable pain secondary to FBSS with intractable neuropathic leg pain when **ALL** of the following criteria are met:

- ◆ Failure of at least six (6) consecutive months of physician-supervised conservative medical management (e.g., pharmacotherapy, physical therapy, cognitive behavioral therapy, or activity lifestyle modification)
 - ◆ Surgical intervention is not indicated or the individual does not wish to proceed with spinal surgery
 - ◆ An attestation by a behavioral health provider (i.e., a face-to-face or virtual assessment with or without psychological questionnaires and/or psychological testing) reveals no evidence of an inadequately controlled mental and/or behavioral health conditions/issues (i.e., substance use disorders, depression, or psychosis) that would impact perception of pain and/or negatively impact the success of a SCS or contraindicate placement of the device
- Permanent implantation of a SCS (i.e., non-high-frequency, HF10 SCS), is considered **medically necessary** for the treatment of chronic intractable pain secondary to FBSS with intractable neuropathic leg pain when at least 50% reduction in pain has been demonstrated during a short-term trial of SCS.

Complex Regional Pain Syndrome (CRPS)/Reflex Sympathetic Dystrophy (RSD)

- A short-term trial (i.e., greater than 48 hours) of a non high-frequency dorsal column spinal cord stimulator (SCS) is considered **medically necessary** for the treatment of chronic, intractable pain secondary to complex regional pain syndrome (CRPS)/reflex sympathetic dystrophy (RSD) only of the upper and lower extremities when **ALL** of the following criteria are met:
- ◆ Diagnosis of CRPS/ RSD as evidenced by **ALL** of the following:
 - Continuing pain that is disproportionate to any inciting event
 - Must report at least one (1) of the symptoms in **EACH** of the following categories:
 - Sensory: reports of hyperesthesia
 - Vasomotor: reports of temperature asymmetry, skin color changes, and/or skin color asymmetry
 - Sudomotor/edema: reports of edema, sweating changes, and/or sweating asymmetry
 - Motor/trophic: reports of decreased range of motion, motor dysfunction (weakness, tremor, dystonia), and/or trophic changes (hair, nail, skin).
 - Must display at least one (1) of the signs on physical examination in **TWO or MORE** the following categories:
 - Sensory: evidence of hyperalgesia (to pinprick) and/or allodynia (to light touch)
 - Vasomotor: evidence of temperature asymmetry, skin color changes, and/or asymmetry
 - Sudomotor/edema: evidence of edema, sweating changes, and/or sweating asymmetry
 - Motor/trophic: evidence of decreased range of motion, motor dysfunction (weakness, tremor, dystonia) and/or trophic changes (hair, nail, skin).

- There is no other diagnosis that better explains the signs and symptoms
 - ◆ Failure of at least six (6) consecutive months of physician-supervised conservative medical management (e.g., pharmacotherapy, physical therapy, cognitive behavioral therapy, or activity lifestyle modification)
 - ◆ Surgical intervention is not indicated
 - ◆ An attestation by a behavioral health provider (e.g., a face-to-face or virtual assessment with or without psychological questionnaires and/or psychological testing reveals no evidence of an inadequately controlled mental and/or behavioral health conditions/issues (i.e., substance use disorders, depression, or psychosis) that would impact perception of pain and/or negatively impact the success of SCS or contraindicate placement of the device
- Permanent implantation of a non-high-frequency dorsal column SCS is considered **medically necessary** for the treatment of chronic, intractable pain secondary to CRPS/RSD when at least a 50% reduction in pain has been demonstrated during a short-term trial of SCS.

Chronic Critical Limb Ischemia (CLI)

- A short-term trial (i.e., greater than 48 hours) of a non-high-frequency dorsal column spinal cord stimulator (SCS) is considered **medically necessary** for the treatment of chronic, intractable pain secondary to chronic critical limb ischemia (CLI) when **ALL** of the following criteria are met:
- ◆ Attestation from a vascular surgeon that the individual is not a suitable candidate for vascular reconstruction.
 - ◆ Diagnosis of critical limb ischemia when **ALL** of the following criteria are met:
 - Ischemic limb rest pain
 - Rutherford Classification Grade II, Category 4 (see table in **Appendix B**) ischemic rest pain characterized by **BOTH** of the following:
 - Resting ankle pressure <40mmHg, flat or barely pulsatile ankle or metatarsal pulse volume recording
 - Toe pressure <30mmHg
 - ◆ Advanced Imaging
 - Angiographic or CT/MR imaging demonstrating multilevel disease with absence of named vessel with flow into the foot
 - ◆ An attestation by a behavioral health provider (i.e., a face-to-face or virtual assessment with or without psychological questionnaires and/or psychological testing reveals no evidence of an inadequately controlled mental and/or behavioral health conditions/issues (e.g., substance use disorders, depression, or psychosis) that would impact perception of pain and/or negatively impact the success of a SCS or contraindicate placement of the device
- Permanent implantation of a non-high-frequency dorsal column SCS is considered **medically necessary** for the treatment of chronic, intractable pain secondary to CLI when beneficial clinical response from a temporarily implanted electrode has been demonstrated prior to consideration of permanent implantation.

Chronic Stable Angina Pectoris

- A short-term trial (i.e., greater than 48 hours) of a non-high-frequency dorsal column SCS is considered **medically necessary** for the treatment of chronic, intractable pain secondary to chronic stable angina pectoris/myocardial ischemia when **ALL** of the following criteria are met:
 - ◆ Angina pectoris is Canadian Cardiovascular Society (CCS) functional class III or class IV (see **Appendix A**)
 - ◆ Attestation the individual's treating cardiologist confirms significant coronary artery disease (CAD) and the individual is not a suitable candidate for a revascularization procedure
 - ◆ Optimal pharmacological treatment using anti-anginal medications (e.g., long-acting nitrates, beta-adrenergic blockers, or calcium-channel antagonists) has failed to adequately improve anginal symptoms
 - ◆ An attestation by a behavioral health provider (i.e., a face-to-face or virtual assessment with or without psychological questionnaires and/or psychological testing reveals no evidence of an inadequately controlled mental and/or behavioral health conditions/issues (e.g., substance use disorders, depression, or psychosis) that would impact perception of pain and/or negatively impact the success of SCS or contraindicate placement of the device.
- Permanent implantation of a non-high-frequency SCS is considered **medically necessary** for the treatment of chronic, intractable pain secondary to chronic stable angina pectoris/myocardial ischemia when a beneficial clinical response from a temporarily implanted electrode has been demonstrated prior to consideration of permanent implantation.

Non-Indications

- A high-frequency spinal cord stimulator (SCS) is considered **experimental, investigational, or unproven (EIU)** for **ANY** other indication, including complex regional pain syndrome (CRPS)/reflex sympathetic dystrophy (RSD).
- A non-high-frequency SCS is considered **EIU** for any other indication including, but not limited to:
 - ◆ Post-amputation pain (phantom limb pain)
 - ◆ Post-herpetic neuralgia
 - ◆ Peripheral neuropathy
 - ◆ Dysesthesias involving the lower extremities secondary to spinal cord injury
 - ◆ Abdominal/pelvic visceral pain
 - ◆ Chronic cervical or lumbar radiculopathy without prior spinal surgery
 - ◆ Failed cervical and/or thoracic spinal surgery with intractable neuropathic pain in arm(s) or trunk.
- Replacement of a functioning non-high-frequency dorsal column SCS with a high-frequency SCS is considered **not medically necessary**.

- Replacement of a dorsal column spinal cord stimulator (SCS) with a dorsal root ganglion (DRG) stimulator is considered **EIU**.
- Dorsal root ganglion stimulation is considered **EIU** for **ALL** indications except as noted below under **Replacement** criteria.

Replacement

- The replacement of an existing high-frequency or non-high-frequency dorsal column spinal cord stimulator (SCS) and dorsal root ganglion (DRG) stimulator is considered **medically necessary** when **ANY** of the following criteria are met:
 - ◆ The existing stimulator and/or battery/generator is malfunctioning, cannot be repaired, and is no longer under warranty.
 - ◆ Revision is required of the electrode percutaneous array(s) or electrode plate/paddle(s).
- Replacement of a malfunctioning dorsal root ganglion (DRG) stimulator with a non-high-frequency or dual-mode dorsal column spinal cord stimulator (SCS) is considered **medically necessary** without a short-term trial (e.g. greater than 48 hours) of the SCS.

Appendix A

New York Heart Association and Canadian Cardiovascular Society Functional Classifications

Class	New York Heart Association Functional Classification	Canadian Cardiovascular Society Functional Classification
I	Patients with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.	Ordinary physical activity does not cause angina, such as walking and climbing stairs. Angina occurs with strenuous or rapid or prolonged exertion at work or recreation.
II	Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.	Slight limitation of ordinary activity. Walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, in cold, in wind, or under emotional stress, or only during the few hours after awakening. Walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions.
III	Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain.	Marked limitation of ordinary physical activity. Walking one to two blocks on the level and climbing one flight in normal conditions and at a normal pace.
IV	Patient with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.	Inability to carry on any physical activity without discomfort—anginal syndrome may be present at rest.
(Heart Failure Society of America [HFSA], 2006; Gibbons, et al., 2002; American Heart Association [AHA], 1994; Canadian Cardiovascular Society [CCS], 1976).		

Appendix B

Rutherford Criteria

Grade	Category	Clinical Description	Objective Criteria
0	0	Asymptomatic- no hemodynamically significant occlusive disease	Normal treadmill or reactive hyperemia test
	1	Mild claudication	Completes treadmill exercise; AP after exercise > 50 mmHg, but at least 20 mmHg lower than resting value
I	2	Moderate claudication	Between categories 1 and 3
	3	Severe claudication	Cannot complete standard treadmill exercise and AP after exercise < 50 mmHg
II	4	Ischemic rest pain	Resting AP < 40 mmHg, flat or barely pulsatile ankle or metatarsal PVR; TP < 30mmHg
III	5	Minor tissue loss non-healing ulcer, focal gangrene with diffuse pedal ischemia	Resting AP < 60 mmHG, ankle or metatarsal PVR flat or barely pulsatile; TP < 40 mmHg
	6	Major tissue loss- extending above TM level, functional foot no longer salvageable	Same as category 5

AP: ankle pressure; PVR: pulse volume recording; TM: transmetatarsal; TP: toe pressure

Procedure (CPT®) Codes

This guideline relates to the CPT® code set below. Codes are displayed for informational purposes only. Any given code’s inclusion on this list does not necessarily indicate prior authorization is required.

CPT®	Code Description/Definition
63650	Percutaneous implantation of neurostimulator electrode array, epidural
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling

This list may not be all inclusive and is not intended to be used for coding/billing purposes. The final determination of reimbursement for services is the decision of the health plan and is based on the individual’s policy or benefit entitlement structure as well as claims processing rules.

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