

# CIGNA MEDICAL COVERAGE POLICIES - MUSCULOSKELETAL CMM-211: Spinal Cord and Dorsal Root Ganglion Stimulation

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**EviCore**  
By EVERNORTH

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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.

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# Definitions

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# Definitions

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## **Complex Regional Pain Syndrome (CRPS) (as defined by the International Association for the Study of Pain [IASP])**

a variety of painful conditions following injury, which appear regionally having a distal predominance of abnormal findings, exceeding in both magnitude and duration, the expected clinical course of the inciting event; and often resulting in significant impairment of motor function, and showing variable progression over time. In addition to injury, CRPS can also occur as a result of various medical disorders or illnesses.

## **Critical Limb Ischemia (CLI)**

clinical syndrome of ischemic pain at rest and ischemic tissue loss such as non-healing ulcers or gangrene, related to peripheral artery disease (PAD) of the lower limbs. Spinal stimulators may be appropriate for the treatment of intractable rest pain secondary to chronic limb ischemia.

## **Dorsal Root Ganglion (DRG) Stimulation**

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. The procedure initially involves a short-term trial (i.e., greater than 48 hours) 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)**

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; basivertebral nerve ablation [BVNA]; etc.) are not considered surgical interventions associated with FBSS

**High-Frequency Spinal Cord Stimulation (HF-SCS) (also referred to as kilohertz frequency spinal cord stimulation or HF10)**

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 frequency in the range of 40-60 Hz 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).

**Ischemic Rest Pain**

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 positioning the limb in a dependent position tends to improve the pain to some degree. The pain is secondary to severe arterial insufficiency resulting in inadequate perfusion to the distal lower extremity.

**Painful Diabetic Peripheral Neuropathy (PDPN)**

a progressive neurological disorder accompanied by neuropathic pain caused by diabetes mellitus.

**Peripheral Nerve Field Stimulation**

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.

- The use of this technology (used alone or in combination with spinal cord stimulation) for treatment of pain conditions is under investigation.

**Peripheral Nerve Stimulation**

involves implantation of electrodes near or on a peripheral nerve to reduce pain.

- The use of this technology (used alone or in combination with spinal cord stimulation) for treatment of pain conditions is under investigation.

**Spinal Cord Stimulation (SCS) (also known as dorsal column stimulation or neuromodulation)**

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 of 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 (e.g., greater than 48 hours) of percutaneous (temporary) spinal cord stimulation, prior to the subcutaneous (permanent) implantation of the spinal cord stimulator, to determine whether the spinal cord stimulator will induce sufficient pain relief to render it medically necessary.

# General Guidelines

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# General Guidelines

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## Application of Guideline

- A dorsal column spinal cord stimulator capable of using either non-high-frequency or high-frequency stimulation (dual-mode) is considered an equally effective alternative (**when the device uses non-high-frequency stimulation**) for the treatment of any of the conditions listed in the **Indications** section below.
- A dorsal column spinal cord stimulator using high-frequency stimulation is considered an equally effective alternative to non-high-frequency dorsal column spinal cord stimulator only for the treatment of chronic, intractable pain secondary to failed back surgery syndrome (FBSS).
- The guideline criteria are not applicable to the following:
  - simple or complex brain neurostimulator pulse generators/transmitters
  - peripheral (i.e., cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generators/transmitters
- The determination of medical necessity for the performance of implantation of a dorsal column spinal cord stimulator SCS is always made on a case-by-case basis.

## Health Equity Considerations

Health equity is the highest level of health for all individuals; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which individuals are born, grow, live, work, and age. Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include the following: safe housing, transportation, and neighborhoods; racism, discrimination, and violence; education, job opportunities, and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

# Indications

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# Failed Back Surgery Syndrome (FBSS)

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## Trial

A short-term trial (i.e., greater than 48 hours) of a non-high-frequency or high-frequency (HF10 SCS) dorsal column spinal cord stimulator is considered **medically necessary** when ALL of the following criteria have been met:

- Performed for the treatment of chronic, intractable pain secondary to failed back surgery syndrome (FBSS) with intractable neuropathic leg pain (after prior surgery in the same spinal region)
- 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
- 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 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 Implant

Permanent implantation of a non-high-frequency or high-frequency (HF10 SCS) dorsal column spinal cord stimulator is considered **medically necessary** when BOTH of the following criteria have been met:

- Must meet ALL criteria for a short-term trial spinal cord stimulator as noted above.
- There has been documented pain relief of at least 50% during a short-term trial of SCS.

# Painful Diabetic Peripheral Neuropathy (PDPN)

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## Trial

A short-term trial (i.e., at least [5] days) of a non-high-frequency or high-frequency (HF10 SCS) dorsal column spinal cord stimulator is considered **medically necessary** when ALL of the following criteria have been met:

- Performed for the treatment of chronic, intractable pain secondary to diabetic peripheral neuropathy in the lower extremities
- Symptoms include BOTH of the following:
  - lower extremity neuropathic pain present for >12 months
  - pain is rated at least VAS  $\geq 5$
- Ineffective pain relief with or intolerance to at least TWO of the following:
  - anticonvulsants
  - tricyclic antidepressant
  - SNRI (serotonin-norepinephrine reuptake inhibitor)
  - opioids
- If taking opioids, the opioid use is  $\leq 100$ MME (morphine milligram equivalent) per day.
- Hemoglobin A1c (HbA1c) <10% within three (3) months prior to trial
- There are no other medical diagnoses (e.g. chronic inflammatory demyelinating polyneuropathy [CIDP]; Hepatitis B; HIV; Lyme disease; chemotherapy or vitamin deficiency induced neuropathy) that are concordant with the presenting symptoms, signs, and results of relevant studies (e.g., imaging, electrodiagnostic testing, laboratory testing, etc.).
- 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 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

Permanent implantation of a non-high-frequency or high-frequency (HF10 SCS) dorsal column spinal cord stimulator is considered **medically necessary** when BOTH of the following criteria have been met:

- Must meet ALL criteria for a short-term trial spinal cord stimulator as noted above.
- There has been documented pain relief of at least 50% during a short-term trial of SCS

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

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## Trial

A short-term trial (i.e., greater than 48 hours) of a non-high-frequency dorsal column spinal cord stimulator is considered **medically necessary** when ALL of the following criteria have been met:

- Performed for the treatment of chronic, intractable pain secondary to CRPS/RSD of the upper and lower extremities
- Diagnostic criteria for CRPS have been met as follows:
  - Presence of continuing pain that is disproportionate to any inciting event
  - Must report at least one (1) symptom in at least THREE (3) of the following categories:
    - Sensory: reports of hyperesthesia (increased sensitivity to sensory stimuli) and/or allodynia (pain to light touch)
    - 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, nails, skin)
  - Must display at least one (1) sign on physical exam at the time of evaluation in at least TWO (2) of the following categories:
    - Sensory: evidence of hyperalgesia (pain to pinprick) and/or allodynia (pain 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, nails, skin)
  - There are no other medical or psychological diagnoses that are concordant with the presenting symptoms, signs, and results of relevant studies (e.g., imaging, electrodiagnostic testing, laboratory testing, etc.).

- The diagnosis is limited to only the extremities and not to the head, face, neck, trunk, perineum, pelvis, or abdominal viscera.
- 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.
- 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 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 Implant

Permanent implantation of a non-high-frequency dorsal column spinal cord stimulator is considered considered **medically necessary** when BOTH of the following criteria have been met:

- Must meet ALL criteria for a short-term trial spinal cord stimulator as noted above.
- There has been documented pain relief of at least 50% during a short-term trial of SCS

# Chronic Critical Limb Ischemia (CLI)

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## Trial

A short-term trial (i.e., greater than 48 hours) of a non-high-frequency dorsal column spinal cord stimulator is considered **medically necessary** when ALL of the following criteria have been met:

- Performed for the treatment of chronic, intractable pain secondary to chronic critical limb ischemia (CLI)
- Attestation from a vascular surgeon that the individual is not a suitable candidate for vascular reconstruction.
- Diagnostic criteria for critical limb ischemia have been met as follows:
  - 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, CT, or MRI) demonstrates multilevel disease with absence of named vessel with flow into the foot.
- 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 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 Implant

Permanent implantation of a non-high-frequency dorsal column spinal cord stimulator is considered **medically necessary** when BOTH of the following criteria have been met:

- Must meet ALL criteria for a short-term trial spinal cord stimulator as noted above.
- There has been documented pain relief of at least 50% during a short-term trial of SCS.

# Chronic Stable Angina Pectoris

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## Trial

A short-term trial (i.e., greater than 48 hours) of a non-high-frequency dorsal column spinal cord stimulator is considered **medically necessary** when ALL of the following criteria have been met:

- Performed for the treatment of chronic, intractable pain secondary to chronic stable angina pectoris/myocardial ischemia
- Angina pectoris is Canadian Cardiovascular Society (CCS) functional class III or class IV (see **Appendix A**)
- Attestation by the individual's treating cardiologist confirms coronary artery disease (CAD) AND the individual is not a suitable candidate for a revascularization procedure
- Failure to adequately improve anginal symptoms with optimal medical treatment (OMT) that includes ALL of the following:
  - anti-platelet therapy
  - statin and/or other lipid-lowering therapy
  - anti-anginal therapy implemented to pursue a goal heart rate of 60 beats per minute
  - anti-hypertensive therapy (as indicated) to pursue a goal systolic blood pressure (SBP) <140mmHg and a goal diastolic blood pressure (DBP) <90mmHg
- 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 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 Implant

Permanent implantation of a non-high-frequency dorsal column spinal cord stimulator is considered **medically necessary** when BOTH of the following criteria have been met:

- Must meet ALL criteria for a short-term trial spinal cord stimulator as noted above.
- There has been a beneficial clinical response during a short-term trial of SCS.

# Replacement

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## Replacement of Dorsal Column Spinal Cord Stimulator

Replacement of an existing non-high-frequency or high-frequency dorsal column spinal cord stimulator is considered **medically necessary** when EITHER of the following criteria have been 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 Dorsal Root Ganglion (DRG) Stimulator

Replacement of an existing dorsal root ganglion (DRG) stimulator with another dorsal root ganglion (DRG) stimulator is considered **medically necessary** when EITHER of the following criteria have been 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).

# Non-Indications

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# Not Medically Necessary

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## Spinal Cord Stimulation (SCS)

- A non-high-frequency dorsal column spinal cord stimulator placed without meeting the criteria in the **Definitions**, the **General Guidelines**, and the **Indications** sections is considered **not medically necessary**.
- A high-frequency dorsal column spinal cord stimulator placed without meeting the criteria in the **Definitions**, the **General Guidelines**, and the **Indications** sections is considered **not medically necessary**.
- If the initial short-term-trial dorsal column spinal cord stimulator fails, a repeat trial is considered **not medically necessary**.
- Replacement of a functioning non-high-frequency dorsal column spinal cord stimulator with a high-frequency dorsal column spinal cord stimulator SCS is considered **not medically necessary**.
- A non-high-frequency or high-frequency dorsal column spinal cord stimulator is considered **not medically necessary** for ANY other indication or condition including, but not limited to, the following:
  - abdominal/pelvic visceral pain
  - abdominal pain related to celiac artery compression syndrome
  - chronic cervical or lumbar radiculopathy without prior spinal surgery
  - chronic cervical, thoracic, or lumbar axial pain without prior spinal surgery
  - dysesthesias involving the lower extremities secondary to spinal cord injury
  - failed cervical and/or thoracic spinal surgery with intractable neuropathic pain in arm(s) or trunk
  - neuropathic pain associated with multiple sclerosis
  - post-amputation pain (phantom limb pain)
  - post-herpetic neuralgia
- Generator modes other than tonic-low and high-frequency (e.g., burst-stimulation) are considered **not medically necessary**.

## Dorsal Root Ganglion (DRG) Stimulator

- Replacement of a dorsal root ganglion (DRG) stimulator with another dorsal root ganglion (DRG) stimulator without meeting the criteria in the **Indications** section is considered **not medically necessary**.
- Replacement of a dorsal column spinal cord stimulator with a dorsal root ganglion (DRG) stimulator is considered **not medically necessary**.

- Initial placement of a dorsal root ganglion (DRG) stimulator is considered **not medically necessary** for ALL indications.

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# Appendix A

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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.
<p>(Heart Failure Society of America [HFSA], 2006; Gibbons, et al., 2002; American Heart Association [AHA], 1994; Canadian Cardiovascular Society [CCS], 1976).</p>		

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# Appendix B

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## Rutherford Classification System for Staging Ischemia

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 >50mmHg, but at least 20mmHg 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 <50mmHg
II	4	Ischemic rest pain	Resting AP <40mmHg, 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 <60mmHg, 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			

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# Codes (CMM-211)

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## Codes (CMM-211)

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The inclusion of any code in this table does not imply that the code is under management or requires prior authorization. Refer to the applicable health plan for management details. Prior authorization of a code listed in this table is not a guarantee of payment. The Certificate of Coverage or Evidence of Coverage policy outlines the terms and conditions of the member's health insurance policy.

Code	Code Description/Definition
<b>63650</b>	Percutaneous implantation of neurostimulator electrode array, epidural
<b>63655</b>	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
<b>63685</b>	Insertion or replacement of spinal neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver

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