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

Effective May 1, 2024

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.

CMM-211: Spinal Cord and Dorsal Root Ganglion Stimulation

Definitions

- **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.
  - **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 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.
- **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, 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 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 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 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 µs and frequencies between 2 and 1200 Hz. Some devices allow adjustment of the settings, including burst- and/or continuous-mode stimulation.

General Guidelines

Application of Guideline

- A dorsal column stimulator capable of **using either high-frequency or non-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 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).
- 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.
- The determination of medical necessity for implantation of a dorsal column spinal cord stimulator (SCS) is always made on a case-by-case basis.

Indications

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

Trial

- A short-term trial (i.e., greater than 48 hours) spinal cord stimulation (i.e., non-high-frequency or high-frequency [HF10 SCS]) is considered **medically necessary** 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) when **ALL** of the following criteria are met:
  - There has been a 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 (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
- If the initial short-term trial fails, a repeat trial is considered not **medically necessary**.

Permanent Implant

- Permanent implantation of a spinal cord stimulator (i.e., non-high-frequency, HF10 SCS) is considered **medically necessary** when **BOTH** of the following criteria are met:
  - Must meet **ALL** criteria for the short-term trial spinal cord stimulation (SCS) as noted above
  - There has been at least a 50% reduction in pain during a short-term trial of SCS

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

Trial

- 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:
  - Limited to only the extremities and not to the head/face/neck, trunk, perineum/pelvis, or abdominal viscera.
  - Diagnosis of CRPS/RSD as evidenced by **ALL** of the following:
    - Continuing pain which is disproportionate to any inciting event
    - Must report at least **ONE** (1) of the symptoms in **THREE of the four** 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) sign on physical examination at the time of evaluation in **TWO or MORE** of 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(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.).
    - 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 (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
- If the initial short-term trial fails, a repeat trial is considered **not medically necessary**

Permanent Implant

- Permanent implantation of a non-high-frequency dorsal column SCS is considered **medically necessary** when **BOTH** of the following criteria are met:
    - Must meet **ALL** criteria for the short-term trial spinal cord stimulation (SCS) as noted above
    - There has been at least a 50% reduction in pain during a short-term trial of SCS

Chronic Critical Limb Ischemia (CLI)

Trial

- 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

- If the initial short-term trial fails, a repeat trial is considered **not medically necessary**

Permanent Implant

- Permanent implantation of a non-high-frequency dorsal column SCS is considered **medically necessary** when **BOTH** of the following criteria are met:
  - Must meet **ALL** criteria for the short-term trial spinal cord stimulation (SCS) as noted above
  - There has been at least a 50% reduction in pain during a short-term trial of SCS

Chronic Stable Angina Pectoris

Trial

- 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 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 by the individual's treating cardiologist confirms significant coronary artery disease (CAD) AND the individual is not a suitable candidate for a revascularization procedure
  - Optimal medical treatment (OMT) that has failed to adequately improve anginal symptoms including **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 may be indicated to pursue a goal systolic blood pressure 9 SBP) of less than 140 mmHG and a goal diastolic blood pressure (DBP) of less than 90 mmHG
  - 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

- If the initial short-term trial fails, a repeat trial is considered **not medically necessary**.

Permanent Implant

- Permanent implantation of a non-high-frequency dorsal column SCS is considered **medically necessary** when **BOTH** of the following criteria are met:
  - Must meet **ALL** criteria for the short-term trial spinal cord stimulation (SCS) as noted above
  - There has been a beneficial clinical response during a short-term trial of SCS

Replacement

Replacement of Dorsal Column Spinal Cord Stimulator

- Replacement of an existing dorsal column spinal cord stimulator (high-frequency or non-high-frequency) 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)

Replacement of Dorsal Root Ganglion (DRG) Stimulator

Placement of a dorsal root ganglion (DRG) stimulation is considered not medically necessary for ALL indications except as noted below.

- Replacement of an existing dorsal root ganglion (DRG) stimulator with another 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)

Non-Indications

Not Medically Necessary

Spinal Cord Stimulation(SCS)

- Spinal cord stimulation (high-frequency or non-high-frequency) placed without meeting the requirements listed in the **Definitions**, the **General Guidelines**, and the **Indications** sections is considered **not medically necessary**.
- Replacement of a functioning non-high-frequency dorsal column SCS with a high-frequency SCS is considered **not medically necessary**.
- A high-frequency spinal cord stimulator (SCS) is considered **not medically necessary** for **ANY** other indication, including complex regional pain syndrome (CRPS)/reflex sympathetic dystrophy (RSD).

- A high-frequency **or** non-high-frequency dorsal column SCS is considered **not medically necessary** for **ANY** other indication including, but not limited to, the following conditions:
  - Post-amputation pain (phantom limb pain)
  - Post-herpetic neuralgia
  - Peripheral neuropathy (e.g., chronic intractable pain from diabetic sensory neuropathy)
  - Dysesthesias involving the lower extremities secondary to spinal cord injury
  - Abdominal/pelvic visceral pain
  - Chronic cervical or lumbar radiculopathy without prior spinal surgery
  - Chronic cervical, thoracic, or lumbar axial pain without prior spinal surgery
  - Failed cervical and/or thoracic spinal surgery with intractable neuropathic pain in arm(s) or trunk.
  - Abdominal pain related to intestinal (mesenteric) ischemic syndrome
  - Neuropathic pain associated with Multiple Sclerosis
- 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 column spinal cord stimulator (SCS) with a dorsal root ganglion (DRG) stimulator is considered **not medically necessary**.
- Dorsal root ganglion (DRG) stimulation is considered **not medically necessary** for **ALL** indications except as noted above in **Replacement**.

Appendices

Appendix A

Classifications of Cardiovascular Disability

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 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 > 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 (CMM-211)

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, requiring pocket creation and connection between electrode array and pulse generator or receiver

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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