



CLINICAL GUIDELINES

CMM-211: Spinal Cord Stimulators

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CMM-211.1: 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 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.
- **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 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 patients with failed back surgery syndrome.
- In contrast to spinal cord stimulation, **peripheral nerve 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 cranial nerve (i.e., vagus nerve, trigeminal nerve), gastric, sacral nerve, and/or posterior tibial nerve stimulation.

- **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.

CMM-211.2: Indications

The determination of medical necessity for implantation of a dorsal spinal cord stimulator is always made on a case-by-case basis.

Chronic Intractable Pain Secondary to Failed Back Surgery Syndrome

- A short-term trial (e.g., greater than 48 hours) spinal cord stimulation [i.e., non high-frequency, high-frequency (HF 10 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:
 - ◆ Failure of at least six consecutive months of physician-supervised conservative medical management (e.g., pharmacotherapy, physical therapy, cognitive therapy, and activity lifestyle modification)
 - ◆ Surgical intervention is not indicated or for patients who do not wish to proceed with spinal surgery
 - ◆ An evaluation by a mental health provider (e.g., a face-to-face assessment with or without psychological questionnaires and/or psychological testing) reveals no evidence of an inadequately controlled mental health problem (e.g., alcohol or drug dependence, depression, 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 spinal cord stimulator (i.e., non high-frequency, HF 10 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 at least a 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) when **ALL** of the following criteria are met:
 - ◆ Diagnosis of complex regional pain syndrome (CRPS)/reflex sympathetic dystrophy (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 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).
 - ◆ Failure of at least six consecutive months of physician-supervised conservative medical management (e.g., pharmacotherapy, physical therapy, cognitive therapy, and activity lifestyle modification)
 - ◆ Surgical intervention is not indicated
 - ◆ An evaluation by a mental health provider (e.g., a face-to-face assessment with or without psychological questionnaires and/or psychological testing reveals no evidence of an inadequately controlled mental health problem (e.g., alcohol or drug dependence, depression, 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 spinal cord stimulator is considered **medically necessary** for the treatment of chronic, intractable pain secondary to complex regional pain syndrome (CRPS)/reflex sympathetic dystrophy (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 (e.g., 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 **BOTH** of the following criteria are met:
 - ◆ Failure of available conventional multidisciplinary medical (e.g., pharmacological, physical therapy) and surgical management (e.g., revascularization)
 - ◆ An evaluation by a mental health provider (e.g., a face-to-face assessment with or without psychological questionnaires and/or psychological testing) reveals no evidence of an inadequately controlled mental health problem (e.g., alcohol or drug dependence, depression, 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 spinal cord stimulator (SCS) is considered **medically necessary** for the treatment of chronic, intractable pain secondary to chronic critical limb ischemia (CLI) when a 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 (e.g., 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 that the individual's treating cardiologist confirms 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 evaluation by a mental health provider (e.g., a face-to-face assessment with or without psychological questionnaires and/or psychological testing) reveals no evidence of an inadequately controlled mental health problem (e.g., alcohol or drug dependence, depression, 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 spinal cord stimulator (SCS) is considered **medically necessary** for the treatment of chronic, intractable pain secondary to chronic stable angina pectoris for myocardial ischemia when a beneficial clinical response from a temporarily implanted electrode has been demonstrated prior to consideration of permanent implantation.

CMM-211.3: Replacement

- The replacement of an existing high frequency or non high-frequency dorsal column spinal cord stimulator (SCS) and/or battery/generator is considered **medically necessary** for an individual when the existing stimulator and/or battery/generator is malfunctioning, cannot be repaired, and is no longer under warranty.
- Replacement of a functioning non high-frequency dorsal column spinal cord stimulator with a high frequency spinal cord stimulator is considered **not medically necessary**.

CMM-211.4: Non-Indications

- A high frequency spinal cord stimulator is considered **experimental, investigational, or unproven** for **ANY** other indication, including CRPS/RSD.
- A non high-frequency dorsal column spinal cord stimulator (SCS) is considered **experimental, investigational or unproven** 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.
- Dorsal root ganglion stimulation is considered **experimental, investigational or unproven** for **ALL** indications.
- Generator modes other than tonic low and high frequency (e.g., burst stimulation) is considered **experimental, investigational, or unproven**.
- Peripheral nerve stimulation, dorsal root ganglion stimulation, including peripheral nerve field stimulation, is considered **experimental, investigational, or unproven** for treatment of acute or chronic pain conditions, including **ANY** of the following:
 - ◆ Failed back surgery syndrome (FBSS) with intractable neuropathic leg pain
 - ◆ Complex regional pain syndrome (CRPS)/reflex sympathetic dystrophy (RSD)
 - ◆ Chronic Critical Limb Ischemia (CLI)
 - ◆ Chronic Stable Angina Pectoris
 - ◆ Post-amputation pain (phantom limb pain)
 - ◆ Post-herpetic neuralgia
 - ◆ Peripheral neuropathy
 - ◆ Dysesthesias involving the lower extremities secondary to spinal cord injury.

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).		

CMM-211.5: 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
63661	Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed
63662	Removal of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed
63663	Revision including replacement, when performed, of spinal neurostimulator electrode
63664	Revision including replacement, when performed, of spinal neurostimulator electrode
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver
95970	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse, amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
95971	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurement(s); simple spinal cord, or peripheral (i.e., peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generation/transmitter, with intraoperative or subsequent programming
95972	Electrode analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurement(s); complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming

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.

CMM-211.6: References

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