MASSACHUSETTS

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Medical Policy

Spinal Cord and Dorsal Root Ganglion Stimulation

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Policy Number: 472

BCBSA Reference Number: 7.01.25 (For Plan internal use only)

Related Policies

Deep Brain Stimulation, #473

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Spinal cord stimulation with standard or high-frequency stimulation may be considered **MEDICALLY NECESSARY** for treatment of severe and chronic pain of the trunk or limbs that is refractory to all other pain therapies when ALL of the following patient criteria are met:

- The treatment is used only as a last resort; other treatment modalities (pharmacologic, surgical, psychological, physical, if applicable) have failed or are judged to be unsuitable or contraindicated;
- Pain is neuropathic in nature (ie, resulting from actual damage to the peripheral nerves). Common indications include, but are not limited to, failed back surgery syndrome, complex regional pain syndrome (ie, reflex sympathetic dystrophy), arachnoiditis, radiculopathies, phantom limb/stump pain, and peripheral neuropathy (including diabetic peripheral neuropathy). Spinal cord stimulation is generally not effective in treating nociceptive pain (resulting from irritation, not damage to the nerves) and central deafferentation pain (related to central nervous system damage from a stroke or spinal cord injury).
- No serious untreated drug habituation exists;
- Demonstration of at least 50% pain relief with a temporarily implanted electrode precedes permanent implantation;
- All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment, and follow-up of the patient are available.

Dorsal root ganglion neurostimulation is considered **MEDICALLY NECESSARY** for the treatment of severe and chronic pain of the trunk or limbs that is refractory to all other pain therapies when ALL of the following patient criteria are met:

- The treatment is used only as a last resort; other treatment modalities (pharmacologic, surgical, psychological, physical, if applicable) have failed or are judged to be unsuitable or contraindicated;
- Pain is neuropathic in nature (ie, resulting from actual damage to the peripheral nerves). Common indications include, but are not limited to, failed back surgery syndrome, complex regional pain syndrome (ie, reflex sympathetic dystrophy), arachnoiditis, radiculopathies, phantom limb/stump pain,

and peripheral neuropathy (including diabetic peripheral neuropathy). Spinal cord stimulation is generally not effective in treating nociceptive pain (resulting from irritation, not damage to the nerves) and central deafferentation pain (related to central nervous system damage from a stroke or spinal cord injury).
- No serious untreated drug habituation exists;
- Demonstration of at least 50% pain relief with a temporarily implanted electrode precedes permanent implantation;
- All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment, and follow-up of the patient are available.

Spinal cord stimulation is considered **INVESTIGATIONAL** in all other situations including, but not limited to, treatment of critical limb ischemia to forestall amputation and treatment of refractory angina pectoris, heart failure, and cancer-related pain.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **required for 63655 & 63685**
Commercial PPO	Prior authorization is **required for 63655 & 63685**

Note: For Commercial Managed Care (HMO and POS) and Medicare HMO Blue℠, the temporary implanted electrode (CPT code 63650) that precedes permanent implantation does not require prior authorization. However, prior authorization is required for the permanent placement of implanted electrodes (CPT codes 63655 and 63685).

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

CPT Codes

CPT codes:	Code Description
63655	Laminectomy for implantation of neurostimulator electrode plate/paddle; epidural
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

CPT Codes

CPT codes:	Code Description
63650	Percutaneous implantation of neurostimulator electrode array; epidural

HCPCS Codes

HCPCS codes:	Code Description
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT and HCPCS codes above if medical necessity criteria are met:

ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
G03.9	Meningitis, unspecified
G56.40	Causalgia of unspecified upper limb
G56.41	Causalgia of right upper limb
G56.42	Causalgia of left upper limb
G57.70	Causalgia of unspecified lower limb
G57.71	Causalgia of right lower limb
G57.72	Causalgia of left lower limb
G60.3	Idiopathic progressive neuropathy
G60.8	Other hereditary and idiopathic neuropathies
G60.9	Hereditary and idiopathic neuropathy, unspecified
G62.89	Other specified polyneuropathies
G62.9	Polyneuropathy, unspecified
G89.21	Chronic pain due to trauma
G89.22	Chronic post-thoracotomy pain
G89.28	Other chronic postprocedural pain
G89.29	Other chronic pain
G89.3	Neoplasm related pain (acute) (chronic)
G89.4	Chronic pain syndrome
G90.511	Complex regional pain syndrome I of right upper limb
G90.512	Complex regional pain syndrome I of left upper limb
G90.513	Complex regional pain syndrome I of upper limb, bilateral
G90.519	Complex regional pain syndrome I of unspecified upper limb
G90.521	Complex regional pain syndrome I of right lower limb
G90.522	Complex regional pain syndrome I of left lower limb
G90.523	Complex regional pain syndrome I of lower limb, bilateral
G90.529	Complex regional pain syndrome I of unspecified lower limb
G90.59	Complex regional pain syndrome I of other specified site
M54.10	Radiculopathy, Site Unspecified
M54.11	Radiculopathy, occipito-atlanto-axial region
M54.12	Radiculopathy, cervical region
M54.13	Radiculopathy, cervicothoracic region
M54.14	Radiculopathy, thoracic region
M54.15	Radiculopathy, thoracolumbar region
M54.16	Radiculopathy, lumbar region
M54.17	Radiculopathy, lumbosacral region

M54.18	Radiculopathy, sacral and sacrococcygeal region
M79.2	Neuralgia And Neuritis, Unspecified
M96.1	Postlaminectomy syndrome, not elsewhere classified

Description

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. In 2015, a spinal cord stimulation device, using a higher frequency (10,000 Hz) than predicate devices, was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. High-frequency stimulation is proposed to be associated with fewer paresthesias, which are a recognized effect of spinal cord stimulation. In 2016, the 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.

The incidence of adverse events related to spinal cord stimulation has been reported to occur in 30% to 40% of cases.[1,] Adverse events can either be hardware-related or biological. Hardware-related complications include lead migration or failure or fracture. Biological complications include infection and pain. More severe biological complications are rare, including dural puncture headache (estimated incidence, up to 0.3%) and neurological damage (estimated incidence, 0.25%).

Other neurostimulators target the dorsal root ganglion. Dorsal root ganglia consist of sensory cell bodies that transmit input from the peripheral nervous system to the central nervous system and play a role in neuropathic pain perception. Dorsal root ganglia are located in the epidural space between spinal nerves

and the spinal cord on the posterior root in a minimal amount of cerebrospinal fluid, amenable to epidural access. Two systems targeting the dorsal root ganglion have received approval or clearance from the FDA.

A retrospective analysis of the FDA's Manufacturer and User Facility Device Experience (MAUDE) database provided information on complications related to the use of dorsal root ganglion stimulation.[2,] The MAUDE database was queried for dorsal root ganglion stimulation reports through 2017, identifying 979 episodes. Complications were predominantly device-related (47%; lead migration and lead damage), with the remaining comprised of procedural complications (28%; infection, new neurologic symptoms, and dural puncture), patient complaints (12%; site pain and unwanted stimulation), serious adverse events (2.4%), and "other" complications (4.6%). The prevalence of complications cannot be estimated using the MAUDE database; while facilities are mandated to report events, patients and health care providers may report events, but are not mandated to do so.

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.[3,] 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 (MRI) 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.

Summary

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 outcome.

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 outcome.

Policy History

Date	Action
10/2022	Policy clarified. Peripheral neuropathy updated to include diabetic peripheral neuropathy.
6/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
6/2022	Prior authorization information clarified for PPO plans. Effective 6/1/2022.
5/2021	BCBSA National medical policy review. Description, summary, and references updated. Policy statements unchanged.
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
6/2020	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
9/2019	BCBSA National medical policy review. New medically necessary indications described. Dorsal root ganglion neurostimulation is considered medically necessary for the treatment of severe and chronic pain of the trunk or limbs. Clarified coding information. Effective 9/1/2019.
1/2019	Clarified coding information.
6/2018	BCBSA National medical policy review. Policy clarified to include burst neurostimulation as an alternate programming of a standard SCS device.
3/2018	Clarified coding information.
12/2017	BCBSA National medical policy review. “Wireless injectable” removed from policy statement on dorsal root ganglion neurostimulation. “Dorsal root ganglion” added to policy title. Effective 12/1/2017.
6/2017	BCBSA National medical policy review. New medically necessary and investigational indications described. Effective 6/1/2017.
9/2016	BCBSA National medical policy review. New investigational indications described. Clarified coding information. Effective 9/1/2016
6/2016	Clarified coding information.
1/2016	Clarified coding information.
6/2015	BCBSA National medical policy review. New investigational indications described. Effective 6/1/2015.
2/2015	Prior authorization clarified for CPT codes 63650 and 63685. Clarified coding information.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
6/2014	BCBSA National medical policy review. New investigational indications described; existing investigational statement modified to state all other situations. Effective 6/1/2014.
12/2013	Removed HCPCS codes C1767, C1816, L8680, and L8682-L8688 as they do not meet the intent of the policy.
10/2013	Removed CPT codes 63661, 63662, 63663, 63664, 63688 and diagnosis codes 337.20 and 722.80 as they do not apply to the policy.
2/2013	New references from BCBSA National medical policy.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
4/2011	BCBSA National medical policy review. No changes to policy statements.

1/2011	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
4/2010	BCSBA National medical policy review. Changes to policy statements.
1/2010	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
1/2009	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
11/2008	Policy 083 effective 11/2008 stating covered and non-covered indications.
1/2008	BCBSA National medical policy review. No changes to policy statements.
1/2008	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
7/2007	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
4/2007	BCBSA National medical policy review. No changes to policy statements.
2/2007	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
1/2007	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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