

Clinical Policy: Spinal Cord Stimulation

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[Coding Implications](#)

[Revision Log](#)

Description

The dorsal column stimulator (DCS), or spinal column stimulator (SCS) is a device that allows for electrical stimulation of the dorsal aspect of the spinal cord nerves in an effort to relieve pain in patients with a variety of chronic pain disorders. In most cases, neuropathic pain responds poorly to standard pharmacological and surgical therapies and can last indefinitely with increasing severity over time. It may result in severe disability. Stimulation in this area interferes with the conduction of pain impulses through adjacent sensory pathways and may stimulate endorphins. The technique does not alter the underlying pathological process. However, in selective patients with persistent and intractable pain of nerve origin, approximately 50 percent of patients will have pain relief, thereby decreasing the need for analgesic medication and at times obviating the need for further surgical procedures.

Policy/Criteria

- I. It is the policy of Pennsylvania Health and Wellness[®] that spinal cord stimulation (SCS) is **medically necessary** for the following indications:
 - A. A *trial of SCS for failed back surgery syndrome* when all the following criteria are met:
 1. Prior lumbar surgery;
 2. Neuropathic pain lasting ≥ 6 months, is refractory and interferes with activities of daily living (ADLs);
 3. Patient is not a candidate for additional surgery;
 4. Patient has failed ≥ 6 months of conventional multidisciplinary medical therapy including all of the following:
 - a. Chiropractic, physical therapy or prescribed home exercise program;
 - b. NSAIDs (non-steroidal anti-inflammatory drugs) unless contraindicated or not tolerated;
 - c. Activity modification;
 5. Patient has demonstrated cognitive ability to manage stimulator;
 6. Patient has no inadequately treated major psychiatric disorders;
 7. Patient is willing to cease any inappropriate drug use prior to implantation.
 - B. A *trial of SCS for complex regional pain syndrome (CRPS)* when all the following criteria are met:
 1. Pain is being managed by a pain management specialist with experience treating CRPS and pain/burning has persisted for > 6 months;
 2. The patient has ≥ 2 of the following symptoms limited to one extremity only:
 - a. Allodynia (pain sensation in response to a typically non-painful stimulus) or hyperalgesia;
 - b. Swelling/tenderness;
 - c. Cyanotic/red/pale digit/extremity;
 - d. Increased sweating;
 - e. Alteration of temperature;
 - f. Persistent loss of motion;

- g. Trophic skin changes;
 - h. Flexion contractures;
 - 3. Pain is chronic, refractory, and interferes with ADLs;
 - 4. Patient has had ≥ 6 months of failed conventional multidisciplinary therapy including all of the following:
 - a. Physical therapy or occupational therapy;
 - b. Anticonvulsant or antidepressant medication;
 - c. Sympathetic block;
 - 5. Patient has demonstrated cognitive ability to manage stimulator;
 - 6. Patient has no inadequately treated major psychiatric disorders;
 - 7. Patient is willing to cease any inappropriate drug use prior to implantation.
- C. *A trial of SCS for chronic ischemic leg pain due to peripheral vascular disease* when all of the following criteria are met:
- 1. Patient has chronic, ischemic leg pain due to peripheral vascular disease and one of the following:
 - a. The patient cannot undergo revascularization;
 - b. Revascularization has failed to relieve painful symptoms and the pain has not responded to medical management;
 - 2. Pain lasting ≥ 6 months, is refractory and interferes with ADLs;
 - 3. Patient has demonstrated cognitive ability to manage stimulator;
 - 4. Patient has no inadequately treated major psychiatric disorders;
 - 5. Patient is willing to cease any inappropriate drug use prior to implantation.
- D. *A trial of SCS for the following indications* has **limited evidence** to prove effectiveness of treatment and consideration will be made on a case by case basis. Medical necessity will be considered in patients based on the following information:
- 1. Patient has chronic, intractable pain due to one of the following:
 - a. Lumbosacral adhesive arachnoiditis secondary to multiple myelographies or lumbar surgeries that has not responded to medical management, including physical therapy (the presence of arachnoiditis is usually documented by the presence of high levels of proteins in the cerebro spinal fluid and/or by myelography or magnetic resonance imaging);
 - b. Nerve root injuries, post-surgical or post traumatic (e.g., avulsion);
 - c. Phantom limb syndrome that has not responded to medical management;
 - d. Post-herpetic neuralgia;
 - e. Plexopathy;
 - f. Polyneuropathy;
 - g. Intercostal neuralgia that did not respond to medical management and nerve blocks;
 - h. Cauda equina injury/syndrome;
 - i. Incomplete spinal cord injury;
 - j. Diabetic neuropathy;
 - 2. Pain lasting ≥ 6 months, is refractory and interferes with ADLs;
 - 3. Patient has failed ≥ 6 months of conventional multidisciplinary medical therapy;
 - 4. Patient has demonstrated cognitive ability to manage stimulator;

5. Patient has no inadequately treated major psychiatric disorders;
 6. Patient is willing to cease any inappropriate drug use prior to implantation.
- E. *A trial of SCS for refractory chronic stable angina pectoris* has **limited evidence** to prove effectiveness of treatment and consideration will be made on a case by case basis. It should be reserved only for carefully selected patients, if any. Medical necessity will be considered in patients based on the following information:
1. Patient has continued angina after percutaneous coronary intervention or coronary artery bypass graft;
 2. Patient is not a candidate for further revascularization;
 3. Patient's angina is NYHA (New York Heart Association) III (less than ordinary physical activity causes symptoms) or IV (symptoms present at rest);
 4. Reversible ischemia documented at least by a symptom-limited treadmill exercise test;
 5. Patient has had optimal pharmacotherapy for at least one month that includes the maximal tolerated dose of at least 2 of the following:
 - a. Long-acting nitrates;
 - b. Beta-adrenergic blockers;
 - c. Calcium channel antagonists;
 6. Pain is chronic, refractory, and interferes with ADLs;
 7. Patient has demonstrated cognitive ability to manage stimulator;
 8. Patient has no inadequately treated major psychiatric disorders;
 9. Patient willing to cease any inappropriate drug use prior to implantation.
- F. *Permanent placement of a SCS* is **medically necessary** following a trial of spinal cord stimulation for an indication listed above when all of the following criteria are met:
1. Disease specific criteria for spinal cord stimulation are met;
 2. Documented trial of ≥ 3 days;
 3. Documented pain reduction of $> 50\%$ from the trial associated with functional improvement;
 4. The same device used for the trial is used for permanent placement.

Background

SCS is currently used to treat a wide variety of inoperable and intractable chronic pain syndromes, including failed back surgery syndrome and CRPS. In patients with failed conservative and surgical treatment of lower-limb ischemia, SCS increases skin blood flow, decreases pain, and improves quality of life. Four studies used inferential statistics and found pain reduction to be significant. At least 50% pain reduction at follow-up was found in 78%, 80%, and 85% of patients in the three studies that reported this data. Follow-up ranged from 6 to 35 months.

According to recent systematic reviews, the most favorable results have been observed in patients with peripheral vascular disease, complex regional pain syndrome, and peripheral neuropathy (e.g., diabetic or causalgic origin). Of interest, the pain relief achieved with SCS in patients with complex regional pain syndrome is possible without vasodilation. The vasodilation found with SCS is attributed to an inhibitory effect on sympathetically maintained

CLINICAL POLICY

Spinal Cord Stimulation

vasoconstriction. Diabetic patients with peripheral arterial occlusive disease who present with intractable pain have also been successfully treated with SCS, except those who have severe autonomic neuropathy. Recently, SCS has been successfully used to treat intractable angina pectoris and chronic mesenteric ischemia.

Spinal cord stimulation is proposed as a late or last resort treatment for chronic pain due to stable angina pectoris. Although most of the research reviewed used subjective outcome measures and some studies lacked prospective design, adequate sample size, and control groups, SCS was shown to alleviate pain and reduce myocardial ischemia in many of the study patients for whom pain relief was previously unobtainable. SCS has also been shown to reduce service utilization in aggregate among recipients. Side effects, while not infrequent, are rarely serious and can usually be resolved by the realignment or replacement of the device. Evidence indicates that the analgesic effect of SCS in angina does not mask the warning pain of myocardial infarction. Patients who have been treated with SCS have not been shown to be at increased risk for morbidity or mortality compared with their peers. Although a minority of patients receiving a trial of SCS ultimately experience prolonged pain relief, the significance of the alleviation of pain and suffering among those who do cannot be underestimated. Therefore, spinal cord stimulation for chronic stable angina pectoris secondary to demonstrable myocardial ischemia in patients who are refractory to treatment should be considered.

Slangen et al (2014) performed a multicenter randomized clinical trial in 36 painful diabetic peripheral neuropathy (PDPN) patients with severe lower limb pain not responding to conventional therapy. The authors concluded treatment success was shown in 59% of patients with PDPN who were treated with SCS over a 6-month period, although this treatment is not without risks. Two year outcomes of the same study reported clinically significant improvements in pain and sleep in 53% of patients. Additionally, a randomized controlled trial of 60 patients, conducted by de Vos and colleagues, found that pain due to PDPN was significantly reduced from baseline at 6 months, and quality of life was improved.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2017, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT® Codes	Description
63650	Percutaneous implantation of neurostimulator electrode array, epidural
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
63685	Incision and subcutaneous placement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling

CLINICAL POLICY
Spinal Cord Stimulation



CPT® Codes	Description
95970	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude, pulse 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, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
95971	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (i.e., peripheral nerve, sacral nerve, , neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
95972	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements: complex spinal cord or peripheral (i.e, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative subsequent programming.

HCPCS Codes	Description
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable includes extension
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
B02.29	Other postherpetic nervous system involvement
E10.40	Type 1 diabetes mellitus with diabetic neuropathy, unspecified
E10.41	Type 1 diabetes mellitus with diabetic mononeuropathy

CLINICAL POLICY
Spinal Cord Stimulation



ICD-10-CM Code	Description
E10.42	Type 1 diabetes mellitus with diabetic polyneuropathy
E10.43	Type 1 diabetes mellitus with diabetic autonomic (poly) neuropathy
E10.49	Type 1 diabetes mellitus with other diabetic neurological complication
E11.40	Type 2 diabetes mellitus with diabetic neuropathy, unspecified
E11.41	Type 2 diabetes mellitus with diabetic mononeuropathy
E11.42	Type 2 diabetes mellitus with diabetic polyneuropathy
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly) neuropathy
E11.49	Type 2 diabetes mellitus with other diabetic neurological complication
G03.1	Chronic meningitis
G09	Sequelae of inflammatory diseases of central nervous system
G54.0-G54.9	Nerve root and plexus disorders
G56.40-G56.42	Causalgia of upper limb
G56.80-G56.82	Other specified mononeuropathies of upper limb
G56.90-G56.93	Unspecified mononeuropathies of upper limb
G57.70-G57.73	Causalgia of lower limb
G57.80-G57.93	Other specified mononeuropathies of lower limb
G90.50-G90.59	Complex regional pain syndrome I (CRPSI)
I20.1	Angina pectoris with documented spasm
I70.221-I70.229	Atherosclerosis of native arteries of extremities with rest pain
I73.9	Peripheral vascular disease, unspecified
M54.10	Radiculopathy, site unspecified
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
M54.30-M54.32	Sciatica
M79.2	Neuralgia and neuritis, unspecified
M96.1	Postlaminectomy syndrome, not elsewhere classified
R20.3	Hyperesthesia
S34.3XX*	Injury of cauda equine
S14.2XX*	Injury of nerve root of cervical spine
S24.2XX*	Injury of nerve root of thoracic spine
S34.21X*	Injury of nerve root of lumbar spine

CLINICAL POLICY
Spinal Cord Stimulation



ICD-10-CM Code	Description
S34.22X*	Injury of nerve root of sacral spine
T87.9	Unspecified complications of amputation stump

*Add 7th digit A-S

Reviews, Revisions, and Approvals	Date	Approval Date

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CLINICAL POLICY

Spinal Cord Stimulation

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