Clinical Policy: Spinal Cord Stimulation

Reference Number: CP.MP.117
Last Review Date: 05/18

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 health plans affiliated with Centene Corporation® 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. Not a candidate for additional surgery;
4. Failure of ≥ 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. Has demonstrated cognitive ability to manage stimulator;
6. No inadequately treated major psychiatric disorders;
7. Willingness 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. 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. Failure of ≥ 6 months of conventional multidisciplinary therapy including all of the following:
   a. Physical therapy or occupational therapy;
   b. Anticonvulsant or antidepressant medication;
   c. Sympathetic block;
5. Has demonstrated cognitive ability to manage stimulator;
6. No inadequately treated major psychiatric disorders;
7. Willingness 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. Chronic, ischemic leg pain due to peripheral vascular disease and one of the following:
      a. Not a candidate for 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. Has demonstrated cognitive ability to manage stimulator;
   4. No inadequately treated major psychiatric disorders;
   5. Willingness 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 members based on the following information:
   1. 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;
      k. Failed Neck Surgery Syndrome (FNSS)

2. Pain lasting ≥ 6 months, is refractory and interferes with ADLs;
3. Failure of ≥ 6 months of conventional multidisciplinary medical therapy;
4. Has demonstrated cognitive ability to manage stimulator;
5. No inadequately treated major psychiatric disorders;
6. Willingness 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 members, if any. Medical necessity will be considered in members based on the following information:
   1. Continued angina after percutaneous coronary intervention or coronary artery bypass graft;
   2. Not a candidate for further revascularization;
   3. 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. 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. Has demonstrated cognitive ability to manage stimulator;
   8. No inadequately treated major psychiatric disorders;
   9. Willingness 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 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

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CPT® Codes	Description
63650	Percutaneous implantation of neurostimulator electrode array, epidural

CPT® Codes	Description
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
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
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
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
Policy split from CP.MP.63 Pain Management Procedures. Added chronic lower limb ischemia indication in I. C per Cochrane review of effectiveness. I.D. Case by-case indications: Added indications in I.D. per American Association of Neurological Surgeons 2008 information on SCS, and 2010 American Society of Anesthesiologists guidelines; added diabetic neuropathy indication. Added requirement for reversible ischemia documented by treadmill exercise test, per inclusion criteria in study by de Jongste. Added ICD-10 codes for diabetic neuropathy.	07/16	07/16
Took out requirement for more than 1 failed back surgery or failed back surgery at more than 1 level in failed back surgery syndrome (FBSS) indication (I.A.), as this was not supported by literature. Specified that pain in FBSS should be neuropathic. Added hyperalgesia as a symptom of CRPS. Coding updated.	07/17	07/17
References reviewed and updated.	05/18	05/18
Added Failed Neck Surgery Syndrome to indications under limited evidence criteria (I.D.1.k). Reviewed by specialist.	9/18	09/18

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.