

Spinal Cord Stimulators (Dorsal Column Stimulators)

Date of Origin:

Last Review Date: 08/22/2018

Effective Date: 08/22/2018

Dates Reviewed: 07/2007, 10/2007, 10/2008, 07/2010, 07/2011, 07/2012, 05/2013, 07/2014, 03/2016, 06/2017, 08/2018

Developed By: Medical Necessity Criteria Committee

I. Description

Spinal cord stimulators, also known as dorsal column stimulators, deliver low voltage electrical stimulation to the dorsal columns of the spinal cord in order to block pain sensations. These devices consist of a lead that delivers the electrical stimulation to the spinal cord, an extension wire that conducts the electrical stimulation from the power source to the lead, and a power source which generates the electrical stimulation. Totally implantable spinal cord stimulators are most commonly used; however, there are also spinal cord stimulators which rely on radio frequency and include a transmitter and an antenna which are carried outside the body and a receiver, which is implanted inside the body. Implantation of the spinal cord stimulator is generally a two-step process. This process includes a trial period of stimulation in which an electrode is temporarily implanted in the epidural space. Once treatment is deemed effective, through a significant reduction in pain, the spinal cord stimulator is permanently implanted. Successful spinal cord stimulation may require extensive programming of the neurostimulators to identify the optimal electrode combinations and stimulation channels. Spinal cord stimulator placement is a non-destructive, reversible procedure and thus is often an attractive alternative for patients who have failed other treatment and surgical options.

II. Criteria: CWQI HCS-0024

- A. Moda Health covers spinal cord stimulators for **1 or more** of the following indications:
- a. Moda Health will cover a trial of spinal cord stimulation for intractable pain to plan limitations when **All** of the following criteria are met:
 - i. Pain is neuropathic with documented pathology related to pain complaint (i.e. abnormal MRI) for 1 or more of the following:
 1. Failed back surgery syndrome.
 2. Complex regional pain syndrome (also known as reflex sympathetic dystrophy).
 3. Inoperable chronic ischemic limb pain secondary to peripheral vascular disease.
 4. Moderate to severe chronic neuropathic pain, including but not limited to, one of the following:
 - a. Arachnoiditis

- b. Radiculopathies
 - c. Phantom limb/stump pain
 - d. Peripheral neuropathy
 - e. Post-herpetic neuralgia
 - f. Incomplete spinal cord injury
 - g. Cauda equina injury
 - ii. Other more conservative methods of pain management have been tried and failed including **1 or more** of the following:
 - 1. For limb ischemia, failed surgical or endovascular revascularization, or inoperable vascular disease
 - 2. For neuropathic pain, stellate ganglion or lumbar sympathetic block
 - 3. Conservative treatment tried and failed for 3 or more months for **ALL** of the following:
 - a. Pharmacological (including NSAIDs, tricyclic antidepressants, and anticonvulsants unless contraindicated or unable to tolerate)
 - b. Physical therapy
 - c. Psychological or cognitive behavioral therapies
 - iii. Patient is not a candidate for further surgical intervention
 - iv. Psychiatric and substance abuse disorders have been ruled out.
 - v. Patient is capable of operating stimulating device and willing to comply with the treatment plan
 - vi. No coagulopathy, severe thrombocytopenia, or anticoagulant or antiplatelet therapy
 - vii. No current or chronic infection
 - viii. Patient has had a face to face evaluation by a psychologist or psychiatrist and cleared for a trial of SCS.
- b. Moda Health will cover the permanent placement of a spinal cord stimulator when **All** of the following criteria are met:
- i. Patient has experienced significant pain reduction of 50% or more with a temporary trial of 3-7 days. *(A spinal cord stimulator trial is considered medically necessary for members who meet the above-listed criteria)*
 - ii. Patient has met criteria for trial placement of a spinal cord stimulator
 - iii. Patient is capable of operating stimulating device and willing to comply with treatment plan
- c. Moda Health will cover a trial of spinal cord stimulation for the management of intractable angina when **All** of the following criteria are met:
- i. Angina is New York Heart Association functional Class III (Symptoms with minimal exertion) or Class IV (Symptoms at rest); and
 - ii. Patient has documented significant coronary artery disease and is not a suitable candidate for revascularization procedures such as coronary artery bypass grafting or coronary angiography
 - iii. Optimal pharmacological treatment has failed to adequately improve anginal symptoms (e.g. long-acting nitrates, beta-adrenergic blockers, or calcium channel antagonists)
 - iv. No history of myocardial infarction or unstable angina in the last 3 months
 - v. No cardiac pacemaker or implantable defibrillator

- vi. No significant valve abnormalities as demonstrated by echocardiography
- vii. No coagulopathy, severe thrombocytopenia, or anticoagulant or antiplatelet therapy
- viii. No current or chronic infection
- d. Moda Health will cover the permanent placement of an implantable spinal cord stimulator for the management of intractable angina for **All** of the following:
 - i. Patient has experienced significant pain reduction of 50% or more with a 3-7 day trial of a temporarily implanted electrode. *(A trial of spinal cord stimulation for the management of angina is considered medically necessary for members who meet the above-listed criteria).*
 - ii. Patient has met criteria for trial placement of a spinal cord stimulator
 - iii. No history of myocardial infarction or unstable angina in the last 3 months
 - iv. No cardiac pacemaker or implantable defibrillator
 - v. No significant valve abnormalities as demonstrated by echocardiography
 - vi. No coagulopathy, severe thrombocytopenia, or anticoagulant or antiplatelet therapy
 - vii. No current or chronic infection
- e. Request for Peripherally implanted nerve stimulation (also known as Percutaneous electrical nerve stimulation (PENS))
Please refer to Electrical Stimulation Devices (for Home use) CWQI: HCS-0027
- f. The requested procedure is **NOT** for Occipital Nerve Stimulators for chronic headache or cervicogenic pain. This is considered experimental and investigational as evidence-based literature has not proven efficacy for this indication. *(Refer to CWQI A-0716 Occipital Nerve Stimulation)*

III. Information Submitted with the Prior Authorization Request:

1. History and physical documenting objective basis for patient's pain
2. Angiography results documenting significant coronary artery disease (for members who are receiving spinal cord stimulation for management of angina)
3. Record of conservative treatment tried including member response to treatment
4. Documentation of clearance by a psychologist or psychiatrist
5. Patient's response to spinal cord stimulator trial if request if for a permanent SCS

IV. CPT or HCPC codes covered:

Codes	Description
63650	Percutaneous implantation of neurostimulator electrode array, epidural
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
63663	Revision of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed
63664	Revision including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminectomy, including fluoroscopy, when performed

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
64555	Peripheral nerve (excludes sacral nerve)
64561	Sacral nerve (transforaminal placement), including image guidance, if performed
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
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, pulse amplitude and 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, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming.
95972	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); complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour
95973	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedure)
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
L8680	Implantable neurostimulator electrode, each
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, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

V. Annual Review History

Review Date	Revisions	Effective Date
05/2013	Annual Review: Added table with review date, revisions, and effective date. Added occipital nerve stimulator for headaches as E/I	05/2013
07/2014	Annual Review: No change	07/2014
09/2015	Annual Review: ICD-10 codes, Updated criteria to meet CMS guideline	09/2015
03/2016	Updated to include CWQI and CMS guidelines in criteria	03/24/2016
06/2017	Annual Review: Updated to new template and minor formatting changes	07/01/2017
8/2018	Annual Review: Added additional chronic neuropathic pain condition.	08/22/2018

VI. References

- Barna S, Hu M, Buxo C, et al. Spinal cord stimulation for treatment of meralgia paresthetica. *Pain Physician*. 2005; 8:315-318. ISSN1533-3159.
- Carter ML. Spinal cord stimulation in chronic pain: a review of the evidence. *Anaesth Intensive Care*. 2004. 32:11-21
- Chou R, Atlas SJ, Stanos SP, Rosenquist RW. Nonsurgical interventional therapies for low back pain: A review of the evidence for an American Pain Society clinical practice guideline. *Spine*. 2009;34(10):1078-1093.
- Clavo B, Robaina F, Catalá L, Lloret M, Pinar B, Caramés MA, Ruiz A, Cabezón A, González G, Lara P, Ruiz-Egea E, Hernández MA. Cerebral blood flow increase in cancer patients by applying cervical spinal cord stimulation. *Neurocirugía (Astur)*. 2007 Feb;18(1):28-32; discussion 33-5.
- de Vos CC, Rajan V, Steenbergen W, et al. Effect and safety of spinal cord stimulation for treatment of chronic pain caused by diabetic neuropathy. *J Diabetes Complications*. 2009;23(1):40-45.
- Di Pede F, Lanza GA, Zuin G, et al. Immediate and long-term clinical outcome after spinal cord stimulation for refractory stable angina pectoris. *Am J Cardiol*. 2003 Apr 15; 91(8):951-5.
- Dumoulin K, Devulder J, Castille F, et al. A psychoanalytic investigation to improve the success rate of spinal cord stimulation as a treatment for chronic failed back surgery syndrome. *Clinical Journal of Pain*. March 1996; 12(1):43-49.

- Dyer MT, Goldsmith K, Khan S, Sharples L, Freeman C, Hardy I, Buxton M, Schofield P. Clinical and cost-effectiveness analysis of an open label, single-centre, randomised trial of spinal cord stimulation (SCS) versus percutaneous myocardial laser revascularisation (PMR) in patients with refractory angina pectoris: The SPiRiT trial. *Trials*. 2008 Jun 30;9:40.
- Ekre O, Norrsell H, Wahrborg P, et al. Temporary cessation of spinal cord stimulation in angina pectoris-effects on symptoms and evaluation of long-term effect determinants. *Coron Artery Dis*. 2003 Jun; 14(4):323-7.
- Frey ME, Manchikanti L, Benyamin RM, et al. Spinal cord stimulation for patients with failed back surgery syndrome: A systematic review. *Pain Physician*. 2009;12(2):379-397.
- Grabow TS, et al. Spinal cord stimulation for complex regional pain syndrome: an evidence-based medicine review of the literature. *Clin J Pain*. 2003. 19:371-83.
- Kapural L, Deer T, Yakovlev A, et al. Technical aspects of spinal cord
- Kemler M, Barendse G, van Kleef M, et al. Spinal cord stimulation in patients with chronic reflex sympathetic dystrophy. *N Engl J Med*. 2000; 343:318-24.
- Kemler MA, de Vet HC, Barendse GA, et al. Effect of spinal cord stimulation for chronic complex regional pain syndrome Type I: Five-year final follow-up of patients in a randomized controlled trial. *J Neurosurg*. 2008;108(2):292-298.
- Klomp HM, Steyerberg EW, Habbema JD, van Urk H; ESES study group. What is the evidence on efficacy of spinal cord stimulation in (subgroups of) patients with critical limb ischemia? *Ann Vasc Surg*. 2009 May-Jun;23(3):355-63.
- Kumar K, Hunter G, Demeria D. Spinal cord stimulation in treatment of chronic benign pain: challenges in treatment planning and present status, a 22-year experience. *Neurosurgery*. March 2006; 58(3):481-496.
- Kumar K, Taylor RS, Jacques L, et al. The effects of spinal cord stimulation in neuropathic pain are sustained: A 24-month follow-up of the prospective randomized controlled multicenter trial of the effectiveness of spinal cord stimulation. *Neurosurgery*. 2008;63(4):762-770; discussion 770.
- Lapenna E, Rapati D, Cardano P, et al. Spinal cord stimulation for patients with refractory angina and previous coronary surgery. *Ann Thorac Surg*. 2006 Nov;82(5):1704-8.
- Lierz P, Gustorff B, Felleiter P. Invasive techniques in pain-management: from infiltration to pump-implantation. *Pain, Symptom Control and Palliative Care*. 2001. Volume 2 Number 1.
- Mailis-Gagnon A, Furlan AD, Sandoval JA, et al. Spinal cord stimulation for chronic pain. *Cochrane Database Syst Rev*. 2006 Issue 2. CD003783.
- Manca A, Kumar K, Taylor RS, et al. Quality of life, resource consumption and costs of spinal cord stimulation versus conventional medical management in neuropathic pain patients with failed back surgery syndrome (PROCESS trial). *Eur J Pain*. 2008;12(8):1047-1058.
- National Institute for Health and Clinical Excellence (NICE). Pain (chronic neuropathic or ischaemic) - spinal cord stimulation. NICE Technology Appraisal Guidance 159. London, UK: NICE; October 2008. Accessed on May 22, 2013 at: <http://www.nice.org.uk/nicemedia/pdf/TA159Guidance.pdf>
- Simpson EL, Duenas A, Holmes MW, et al. Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin: Systematic review and economic evaluation. *Health Technol Assess*. 2009;13(17):iii, ix-x, 1-154.
- Sparkes E, Raphael JH, Duarte RV, LeMarchand K, Jackson C, Ashford RL. A systematic literature review of psychological characteristics as determinants of outcome for spinal cord stimulation therapy. *Pain*. 2010 Aug;150(2):284-9.

- stimulation for managing chronic visceral abdominal pain: The results from the national survey. Pain Med. 2010;11(5):685-691.
- Taylor RS, De Vries J, Buchser E, Dejongste MJ. Spinal cord stimulation in the treatment of refractory angina: systematic review and meta-analysis of randomised controlled trials. BMC Cardiovasc Disord. 2009 Mar 25;9:13..
- Taylor RS, et al. The cost effectiveness of spinal cord stimulation in the treatment of pain: a systematic review of the literature. J Pain Symptom Manage. 2004. 27:370-8.
- Taylor RS. Spinal cord stimulation in complex regional pain syndrome and refractory neuropathic back and leg pain/failed back surgery syndrome: results of a systematic review and meta-analysis. J Pain Symptom Manage. 2006 Apr;31(4 Suppl):S13-9.
- Turner J A, Loeser J D, Bell K G, Spinal cord stimulation for chronic low back pain: a systematic literature synthesis. (Cochrane Review). In: The Cochrane Library, Issue 1, 2006. Oxford: Update Software.
- Yu W, Edner M, Hellstrom K, et al. Spinal cord stimulation for refractory angina pectoris: a retrospective analysis of efficacy and cost-benefit. Coron Artery Dis. 2004 Feb; 15(1):31-7.
- Zhou Y, Furgana F, Zhang Y. Quality assurance for interventional pain management procedures. Pain Physician. 2005; 9:107-114. ISSN 1533-3159.
- Centers for Medicare & Medicaid Services; National Coverage Determination (NCD) for Electrical Nerve Stimulators (160.7); Effective Date 8/7/1995
- Physician Advisors

Appendix 1 – Applicable ICD-10 diagnosis codes:

Codes	Description
B02.29	Other postherpetic nervous system involvement
G03.1	Chronic meningitis
G54.0-G54.9	Nerve root and plexus disorders
G56.4-G56.42	Causalgia of upper limb
G56.8-G56.92	Other specified mononeuropathies of unspecified upper limb
G57.70-G57.72	Causalgia of lower limb
G57.80-G57.9	Other specified mononeuropathies of lower limb
G89.2-G89.4	Chronic pain, not elsewhere classified
G90.50-G90.9	Complex regional pain syndrome I (CRPSI)
I20.0	Unstable angina
I70.22-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
R52	Pain, unspecified
S34.3XXS	Injury of cauda equine
S14.2XXA	Injury of nerve root of cervical spine
S24.2XXA	Injury of nerve root of thoracic spine, initial encounter
S34.21XA	Injury of nerve root of lumbar spine, initial encounter
S34.22XA	Injury of nerve root of sacral spine, initial encounter
T87.9	Unspecified complications of amputation stump

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5, 8	NCD/LCD Document (s):
National Coverage Determination 160.7 Electrical Nerve Stimulators	
https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=240&ncdver=1&DocID=160.7&kq=true&bc=gAAAABAAAAAAAA%3d%3d&	

NCD/LCD Document (s):

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC