LCD - Spinal Cord Stimulation for Chronic Pain (L36035)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
First Coast Service Options, Inc.	A and B MAC	09101 - MAC A	J - N	Florida
First Coast Service Options, Inc.	A and B MAC	09102 - MAC B	J - N	Florida
First Coast Service Options, Inc.	A and B MAC	09201 - MAC A	J - N	Puerto Rico Virgin Islands
First Coast Service Options, Inc.	A and B MAC	09202 - MAC B	J - N	Puerto Rico
First Coast Service Options, Inc.	A and B MAC	09302 - MAC B	J - N	Virgin Islands

LCD Information

Document Information

LCD ID
L36035

LCD Title
Spinal Cord Stimulation for Chronic Pain

Proposed LCD in Comment Period
N/A

Source Proposed LCD
N/A

Original Effective Date
For services performed on or after 10/01/2015

Revision Effective Date
For services performed on or after 11/28/2019

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date

N/A

Notice Period End Date
N/A

CMS National Coverage Policy

This LCD supplements but does not replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for Spinal Cord Stimulation for Chronic Pain. Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify or supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for Spinal Cord Stimulation for Chronic Pain and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies may be found in the following Internet-Only Manuals (IOMs) published on the CMS Web site.

Internet Only Manual (IOM) Citations:

- CMS IOM Publication 100-03, *Medicare National Coverage Determinations (NCD) Manual*,
    - Chapter 1, Part 2, Section 160.2 Treatment of Motor Function Disorders with Electric Nerve Stimulation, Section 160.7 Electrical Nerve Stimulators
- CMS IOM Publication 100-04, *Medicare Claims Processing Manual*,
    - Chapter 23, Section 20.9 National Correct Coding Initiative (CCI)
- CMS IOM Publication 100-08, *Medicare Program Integrity Manual*,
    - Chapter 13, Section 13.5.4 Reasonable and Necessary Provision in an LCD

Social Security Act (Title XVIII) Standard References:

- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.
- Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.
- Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

History/Background and/or General Information

Spinal cord (dorsal column) stimulation (SCS) is a pain relief technique that delivers a low-voltage electrical current to the spinal cord to block the sensation of pain. This technique is best suited for pain that is neuropathic in nature i.e., resulting from actual damage to the peripheral nerves. Common indications include, but are not limited to, failed back syndrome, complex regional pain syndrome (i.e., reflex sympathetic dystrophy), arachnoiditis, radiculopathies, phantom limb/stump pain, peripheral neuropathy. SCS 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).

Two stages are involved in SCS implantation. In both stages, a physician, guided by an x-ray, places a lead into the epidural space located within the bony spinal canal.

The first stage consists of a short trial (e.g., 3-14 days) with a temporary percutaneous implantation of neurostimulator electrode(s) and external generator for assessing the patient's suitability for ongoing treatment with a permanent surgically implanted nerve stimulator. During the trial phase, one or two leads are placed via an epidural needle in the appropriate position. This can be done under light sedation in an office setting if all the sterility, equipment, professional training and support personnel required for the proper surgery and follow up of the patient are available. If at least 50% pain relief is achieved during the trial phase, the temporary system may be transitioned to a permanent system. Performance and documentation of an effective trial is a prerequisite for permanent nerve stimulation.

In the permanent implantation stage, there are two different SCS systems routinely used. The first system uses percutaneous insertion of electrodes into the epidural space and subcutaneous connection to a neurostimulator. The second system involves the implantation of paddle-type leads into the epidural space after laminectomy and subcutaneous connection to a neurostimulator. Neurostimulators may be either Implantable Pulse Generators (IPGs), which use either a non-rechargeable or a rechargeable internal battery, or radio frequency devices, which receive energy in the form of radio frequency pulses from an external device powered by a rechargeable battery. The appropriate SCS system with up to 16 contacts/electrodes will depend on the underlying condition, the patient's pain patterns, the area of body affected, and the amount and intensity of stimulation required. Permanent neurostimulators must be placed in an Ambulatory Surgical Center (ASC) or hospital.

Covered Indications

SCS may be covered for the relief of chronic intractable pain under the following circumstances:

- To treat chronic pain caused by lumbosacral arachnoiditis that has not responded to medical management including physical therapy. (Presence of arachnoiditis is usually documented by presence of high levels of proteins in the Cerebrospinal Fluid (CSF) and/or by myelography or Magnetic Resonance Imaging (MRI)
- To treat intractable pain caused by nerve root injuries, post-surgical or post-traumatic including that of post-laminectomy syndrome (failed back syndrome).
- To treat intractable pain caused by complex regional pain syndrome I & II.
- To treat intractable pain caused by phantom limb syndrome that has not responded to medical management.
- To treat intractable pain caused by end-stage peripheral vascular disease, when the patient cannot undergo revascularization or when revascularization has failed to relieve painful symptoms and the pain has not responded to medical management.
- To treat intractable pain caused by post-herpetic neuralgia.
- To treat intractable pain caused by cauda equina injury.
- To treat intractable pain caused by incomplete spinal cord injury.
- To treat intractable pain caused by plexopathy.

Limitations

SCS is considered experimental or investigational for all other indications including, but not limited to, treatment for refractory angina pectoris and treatment of cancer-related pain. There is insufficient evidence to conclude that SCS improves net health outcomes.

Selection of patients for implantation of spinal cord stimulators is critical to success of this therapy. No payment may be made for the implantation of spinal cord (dorsal column) stimulators or services and supplies related to such

implantation, unless all of the conditions listed below have been met:

- Patients being selected for a trial must not have current substance abuse;
- Patients must undergo proper patient education, discussion, and disclosure including an extensive discussion of the risks and benefits of this therapy; and
- Only patients who experience a positive response to a trial should proceed to a permanent implantation. All trials which proceed to permanent implant must have adequate documentation in the chart to support that decision. A successful trial should be associated with at least a 50% reduction of target pain, or 50% reduction of analgesic medications, and show some element of functional improvement. (Patients with reflex sympathetic dystrophy may show lower levels of improvement since it takes longer periods for improvement than the typical 1-2 week trial). Physician judgment and experience will also be taken into account.
- Please refer to CMS IOM Publication 100-03, *Medicare National Coverage Determinations (NCD) M*anual; Chapter 1, Part 2, Section 160.2 Treatment of Motor Function Disorders with Electric Nerve Stimulation, Section 160.7 Electrical Nerve Stimulators for additional limitations.

Percutaneous implantation of neurostimulator electrode array, epidural - Two temporary spinal cord stimulator trials per anatomic spinal region (two per DOS) or (four units) per patient per lifetime, in place of service office, ASC, out-patient hospital, or hospital. Since permanent neurostimulator arrays can also be placed percutaneously, percutaneous implantation of neurostimulator electrode array, epidural can be covered more often in place of service ASC, outpatient hospital, or hospital.

Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural - One permanent spinal cord stimulator per patient per lifetime performed in an ASC, outpatient hospital, or hospital.

Removal of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed and Revision Including Replacement, When Performed, of Spinal Neurostimulator Electrode Percutaneous Array(S), Including Fluoroscopy, When Performed will not be reimbursed in the office setting since they are included in Percutaneous Implantation of Neurostimulator Electrode Array, Epidural.

If a trial fails, a repeat trial is not appropriate unless there are extenuating circumstances that lead to trial failure.

Generally, electronic analysis is not considered medically necessary when provided at a frequency more often than once every 30 days. More frequent analysis may be necessary in the first month after implantation.

Relative Contraindication to SCS:

- The presence of other stimulation devices with sensing capacities (e.g., pacemakers or implantable cardiac defibrillators could be interfered by a spinal cord stimulator). This is a relative contraindication that may be covered when the patient has indications for a SCS and the documentation entails that the beneficiary was informed of their treatment options and explained the risks/benefits of SCS.

Contraindications to SCS:

- Major psychiatric disorders, including somatization;
- No partial sparing of the dorsal column fibers (e.g., total paraplegia) of the treated area;
- Severe diseases likely to interfere with neuromodulation procedures (e.g., coagulopathies and immunodeficiency diseases);
- An active and untreated substance abuse disorder;

- Ongoing requirement for therapeutic diathermy; or
- Severe cognitive impairment rendering a patient incapable of giving informed consent for the procedure and/or operating the device.

As published in the CMS IOM Publication 100-08, *Medicare Program Integrity Manual*, Chapter 13, Section 13.5.4, an item or service may be covered by a contractor LCD if it is reasonable and necessary under the Social Security Act Section 1862 (a)(1)(A). Contractors shall determine and describe the circumstances under which the item or service is considered reasonable and necessary.

Provider Qualifications

The CMS IOM Publication 100-08, *Medicare Program Integrity Manual*, Chapter 13, Section 13.5.4, outlines that "reasonable and necessary" services are "ordered and furnished by qualified personnel." Services will be considered medically reasonable and necessary only if performed by appropriately trained providers. A qualified physician for this service/procedure is defined as follows: A) Physician is properly enrolled in Medicare. B) Training and expertise must have been acquired within the framework of an accredited residency and/or fellowship program in the applicable specialty/subspecialty in the United States or must reflect equivalent education, training, and expertise endorsed by an academic institution in the United States and/or by the applicable specialty/subspecialty society in the United States.

Permanent neurostimulators must be placed in an ASC or hospital. Physicians performing SCS trials in the office setting will be considered qualified if they have like privileges at a local hospital or ASC, or the providers have one of the following applicable specialty/subspecialty; Pain Medicine, Interventional Pain, Neurosurgery, Physical Medicine and Rehabilitation, Orthopedic Surgery. It is preferable that physicians performing the SCS trial will also perform the permanent implant. If the physician implanting the trial neurostimulator does not or cannot implant the permanent neurostimulator, the patient should be informed of this in writing and given the name of the referral surgeon who will implant the permanent neurostimulator(s).

Physicians with a low trial to permanent implant ratio (less than 50%) may be subject to post-payment review and may be asked to submit documentation as to the patient selection criteria, the radiologic imaging demonstrating proper lead placement, and the medical necessity of the trials. Failure to provide this documentation will be cause for post-payment denial and recoupment of reimbursement. It is understood that all patients may not have a favorable result of the trial implant; but careful selection should find the most appropriate patients.

Summary of Evidence

N/A

Analysis of Evidence (Rationale for Determination)

N/A

General Information

Associated Information

Documentation Requirements

Please refer to the Local Coverage Article: Billing and Coding: Spinal Cord Stimulation for Chronic Pain (A57709) for documentation requirements that apply to the reasonable and necessary provisions outlined in this LCD.

Utilization Guidelines

Please refer to the Local Coverage Article: Billing and Coding: Spinal Cord Stimulation for Chronic Pain (A57709) for utilization guidelines that apply to the reasonable and necessary provisions outlined in this LCD.

Sources of Information

1. American Society of Anesthesiologists Task Force on Chronic Pain Management; American Society of Regional Anesthesia and Pain Medicine. Practice guidelines for chronic pain management: an updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. Apr 11, 2011. Accessed Sept. 11, 2014
2. Boswell MV, Trescot AM, et.al. (2007) American Society of Interventional Pain Physicians. Interventional Techniques: Evidence-based Practice Guidelines in the Management of Chronic Spinal Pain. *Pain Physician;* 10(1): 7-111.
3. Chou R, Atlas SJ, et.al. (2009) Nonsurgical interventional therapies for low back pain: A review of the evidence for an American Pain Society clinical practice guideline. *Spine;* 34(10):1078-1093.
4. de Vos C., Rajan V, et al. (2009) Effect and safety of spinal cord stimulation for treatment of chronic pain caused by diabetic neuropathy. *J Diabetes Complications;23*(1):40-45
5. Dworkin R., O'Connor A., et.al. (2013) Interventional management of neuropathic pain: NeuPSIG recommendations. *Pain;* 154(11):2249-61.
6. Feingerg, S., Leong, M. et.al. (2014) American Chronic Pain Association (ACPA) Resource Guide to Chronic Pain Medication & Treatment. 2014 edition American Academy of Pain Medicine (AAPM), American Pain Society. Accessed on September 15, 2014
7. Kumar K, Taylor R., et al. (2008) 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;* 63(4):762-770.
8. Lihua P, Su M, et al. (2013) Spinal cord stimulation for cancer-related pain in adults. *Cochrane Database Syst Rev;* 2:1-26.
9. Mailis A, Taenzer P. (2012) Evidence-based guideline for neuropathic pain interventional treatments: spinal cord stimulation, intravenous infusions, epidural injections and nerve blocks. *Pain Res Manag;* 17(3):150-8.
10. Manca A, Kumar K, et al. (2008) 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;12*(8):1047-1058.
11. Manchikanti L, Falco FJ, et.al. (2013) An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part I: introduction and general considerations. *Pain Physician:* S1-48. Accessed September 11, 2014
12. National Institute for Health and Clinical Excellence (NICE). TA159 Pain (chronic neuropathic or ischaemic) - spinal cord stimulation: guidance. (2008). Accessed Jul 31, 2013.
13. North R, Shipley J, et.al. (2007) American Academy of Pain Medicine. Practice parameters for the use of spinal cord stimulation in the treatment of chronic neuropathic pain. *Pain Med;* 8 Suppl 4:S200-75.
14. Ontario Ministry of Health and Long Term Care, Medical Advisory Secretariat. Spinal cord stimulation for the management of neuropathic pain. (2005)Health Technology Literature Review. Toronto, ON: Ontario Ministry of Health and Long Term Care; Accessed on September 15, 2014.
15. Pedrini L, Magnoni F. (2007) Spinal cord stimulation for lower limb ischemic pain treatment. *Interact Cardiovasc Thorac Surg.* (4):495-500.
16. Shahbazian M., Richeimer S. (2011)Implant Technologies for Severe Pain: Why, When and the Outcomes. *Practical Pain Management;11*(8):73-9.
17. Spinal Cord Stimulation October, 2008 American Association of Neurological Surgeons. Accessed on September

15, 2014.
18. Turner J, Loeser J, et.al. (2004) Spinal cord stimulation for patients with failed back surgery syndrome or complex regional pain syndrome: A systematic review of effectiveness and complications. *Pain;108*(1-2):137-147.
19. Ubbink D, Vermeulen H. (203) Spinal cord stimulation for non-reconstructable chronic critical leg ischaemia. Cochrane Database of Systematic Reviews 2013, Issue 2. Accessed on September 11, 2014.

Bibliography

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
11/28/2019	R7	Revision Number: 6 Publication: November 2019 Connection LCR A/B2019-075 Explanation of Revision: Based on Change Request (CR) 10901, the LCD was revised to remove all billing and coding and all language not related to reasonable and necessary provisions ("Bill Type Codes," "Revenue Codes," "CPT/HCPCS Codes," "ICD-10 Codes that Support Medical Necessity," "Documentation Requirements" and "Utilization Guidelines" sections of the LCD) and place them into a newly created billing and coding article. During the process of moving the ICD-10-CM diagnosis codes to the billing and coding article, the ICD-10-CM diagnosis code ranges were broken out and listed individually. In addition, the Social Security Act and Internet Only Manual (IOM) reference sections were updated. The effective date of this revision is for claims processed on or after January 8, 2019, for dates of service on or after October 3, 2018. At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination and therefore not all the fields included on the LCD are applicable as noted in this LCD.	• Other (Revision based on CR 10901)
01/22/2019	R6	Revision Number: 5 Publication: February 2019 Connection LCR A/B2019-011	• Other (Revisions based on review)

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		Explanation of revision: Based on a review of the LCD, grammatical errors were corrected. Also, in the second bullet under the "Limitations" section of the LCD, "item a" was replaced with "Implanted Peripheral Nerve Stimulators" to be consistent with NCD 160.7 language. The effective date of this revision is based on process date. In addition, based on CR 10901, the "Training and Qualifications" section of the LCD was revised to update the section number for Pub. 100-08, Chapter 13, from 13.5.1 to 13.5.4. Also, "Pub. 100-08, Chapter 13, Section 13.5.4" was added to the "CMS National Coverage Policy" section of the LCD. The effective date of this revision is for claims processed on or after 01/08/2019, for dates of service on or after 09/26/2018. 01/22/2019: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination and therefore not all the fields included on the LCD are applicable as noted in this LCD.	
01/01/2019	R5	Revision Number: 4 Publication: December 2018 Connection LCR A/B2019-001 Explanation of revision: Annual 2019 HCPCS Update, the descriptors for CPT codes 95970, 95971 and 95972 were revised. The effective date of this revision is based on date of service. 01/01/2019: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination and therefore not all the fields included on the LCD are applicable as noted in this LCD.	• Revisions Due To CPT/HCPCS Code Changes
02/08/2018	R4	Revision Number: 3 Publication: February 2018 Connection LCR A/B2018-012 Explanation of Revision: This LCD has been revised to include an explanation that all the codes within the asterisked range	• Provider Education/Guidance • Public Education/Guidance

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		from the first code to the last code apply in the "Group 1 Medical Necessity ICD-10 Codes Asterisk Explanation:" for the code ranges in the "ICD-10 Codes that Support Medical Necessity" "Group 1 Codes:" section of the LCD. The effective date of this revision is based on process date. 02/08/2018: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination and therefore not all the fields included on the LCD are applicable as noted in this policy.	
10/01/2016	R3	Revision Number: 2 Publication: October 2016 Connection LCR A/B2016-097 Explanation of Revision: Based on CR 9677 (Annual 2017 ICD-10-CM Update) the LCD was revised. Added code G56.43 to range G56.40-G56.42 and revised range to read G56.40-G56.43; added code G56.93 to range G56.80-G56.92 and revised range to read G56.80-G56.93; added G57.73 to range G57.70-G57.72 and revised range to read G57.70-G57.73; added code G57.83 to range G57.80-G57.82 and revised range to read G57.80-G57.83; added code G57.93 to range G57.90-G57.92 and revised range to read G57.90-G57.93. Deleted diagnosis range T85.81XA-T85.89XS and added diagnosis range T85.810A-T85.898S. The effective date of this revision is based on date of service.	• Revisions Due To ICD-10-CM Code Changes
01/01/2016	R2	Revision Number: 1 Publication: December 2015 Connection LCR A/B2016-021 Explanation of Revision: Annual 2016 HCPCS Update. Descriptor revised for CPT code 95972 and CPT code 95973 was deleted. The effective date of this revision is based on date of service.	• Revisions Due To CPT/HCPCS Code Changes
10/01/2015	R1	7/30/15- - The language and/or ICD-10-CM diagnoses were updated to be consistent with the current ICD-9-CM LCD's language and coding.	• Provider Education/Guidance

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

A57709 - Billing and Coding: Spinal Cord Stimulation for Chronic Pain

Related National Coverage Documents

NCDs

160.7 - Electrical Nerve Stimulators

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
11/21/2019	11/28/2019 - N/A	Currently in Effect (This Version)
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.		

Keywords

N/A