

Local Coverage Determination (LCD): Spinal Cord Stimulators for Chronic Pain (L35136)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	A and B MAC	01111 - MAC A	J - E	California - Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern
Noridian Healthcare Solutions, LLC	A and B MAC	01211 - MAC A	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01311 - MAC A	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01911 - MAC A	J - E	American Samoa California - Entire State Guam Hawaii Nevada Northern Mariana Islands

LCD Information

Document Information

LCD ID

Original Effective Date

L35136

For services performed on or after 10/01/2015

LCD Title

Spinal Cord Stimulators for Chronic Pain

Revision Effective Date

For services performed on or after 12/01/2019

Proposed LCD in Comment Period

N/A

Revision Ending Date

N/A

Source Proposed LCD

DL35136

Retirement Date

N/A

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Notice Period Start Date

04/14/2016

Notice Period End Date

05/31/2016

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CMS National Coverage Policy

Title XVIII of the Social Security Act (SSA), §1862(a)(1)(A), states that no Medicare payment shall be made for

items or services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”

CMS Manual System, Pub 100-03, *Medicare National Coverage Determinations Manual*, Chapter 1, §160.7, Electrical Nerve Stimulators.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

The implantation of spinal cord stimulators (SCS) may be covered as therapies for the relief of chronic intractable pain. SCS is best suited for neuropathic pain but may have some limited value in other types of nociceptive severe, intractable pain. Therapy consists of a short trial with a percutaneous implantation of neurostimulator electrode(s) in the epidural space for assessing a patient’s suitability for ongoing treatment with a permanent surgically implanted nerve stimulator. Performance and documentation of an effective trial is a prerequisite for permanent nerve stimulation. In situations where the spinal cord stimulator has been working well but is in need of replacement for battery change, malfunction or end of stimulator life, a new trial is not needed to replace the stimulator.

Selection of patients for implantation of spinal cord stimulators is critical to success of this therapy. SCS therapy should be considered as a late option after more conservative attempts such as medications, physical therapy, psychological therapy or other modalities have been tried.

Patients must have undergone careful screening, evaluation and diagnosis by a multidisciplinary team prior to implantation. (Such screening must include psychological, as well as physical evaluation). Documentation of the history and careful screening must be available in the patient chart if requested. Patients being selected for a trial

- Must not have active substance abuse issues.
- Must undergo proper patient education, discussion, and disclosure including an extensive discussion of the risks and benefits of this therapy.
- Must undergo appropriate psychological screening

Many experts recommend that the temporary neurostimulator be placed in an ASC or outpatient hospital setting. However, the temporary neurostimulator trial can be done 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. Permanent neurostimulators must be placed in an ASC or hospital. Physicians performing SCS trials in the office setting must have like privileges at a local hospital or ASC, or the providers must be sub-specialty boarded in Pain Medicine by the American Board of Anesthesiology.

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).

It is expected that accurate patient selection will lead to most patients going on to receive permanent implants. 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.

Physicians with a low trial to permanent implant ratio (less than 50%) will 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.

Noridian will reimburse for placement of a maximum of 2 leads or 16 "contacts," and for 2 SCS trials per anatomic spinal region per patient per lifetime (with exceptions allowed for technical limitations for the initial trials or for use of different modalities of stimulation, including new technology). More than 2 SCS trials per anatomic spinal region per patient per lifetime is not considered reasonable and necessary.

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

Summary of Evidence

NA

Analysis of Evidence (Rationale for Determination)

NA

General Information

Associated Information

This final LCD, effective 06/01/2016, combines JEA DL36200 into the JEB LCD so that both JEA and JEB contract numbers will have the same final MCD LCD number.

Sources of Information

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2. McIntyre PJ, Bedder MD. Complications of Spinal Cord Stimulation. In: Deer TR, Editor. Neurostimulation for the Treatment of Chronic Pain. *Interventional and Neuromodulatory Techniques for Pain Management Series* Philadelphia, PA: Elsevier Saunders; 2011:1-15-134.
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6. Shahbazian MS, Richeimer SH. Implant Technologies for Severe Pain: Why, When and the Outcomes. *Practical Pain Management*. Oct 2011;11(8):73-9.

7. Wu C, Falowski SM, Sharan A. Spinal Cord Stimulation: General Indications. In: Deer TR, Editor. Neurostimulation for the Treatment of Chronic Pain. *Interventional and Neuromodulatory Techniques for Pain Management Series*. Philadelphia, PA: Elsevier Saunders; 2011: 1-5-39.

Bibliography

NA

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
12/01/2019	R9	<p>The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.</p> <p>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.</p>	<ul style="list-style-type: none"> Other (The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.)
12/01/2019	R8	<p>The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.</p> <p>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.</p>	<ul style="list-style-type: none"> Other (The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.)
12/01/2019	R7	As required by CR 10901, all billing and coding	<ul style="list-style-type: none"> Revisions Due To Code Removal

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		<p>information has been moved to the companion article; this article is linked to the LCD.</p> <p>12/01/2019: 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 policy.</p>	
10/01/2019	R6	<p>Per the annual update effective 10/01/2019, the ICD-10 code description Z45.42 - Encounter for adjustment and management of neuropacemaker (brain) (peripheral nerve) (spinal cord) was changed to Z45.42 - Encounter for adjustment and management of neurostimulator.</p> <p>10/01/2019 - 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 policy.</p>	<ul style="list-style-type: none"> • Revisions Due To ICD-10-CM Code Changes
10/01/2017	R5	<p>DATE (08/16/2017): 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.</p> <p>Effective DOS on or after 6/1/16, CPT® codes 63661, 63662, 63688, and 95970-95972 are removed from this LCD. These procedure codes may be used for services unrelated to this LCD and are not subject to the DX criteria in the LCD.</p> <p>Effective DOS 10/01/2017, ICD-10-CM M48.06 was deleted. ICD-10-CM codes M48.061 and</p>	<ul style="list-style-type: none"> • Revisions Due To ICD-10-CM Code Changes • Other (CPT® codes 63661, 63662, 63688, and 95970-95972 are used for conditions unrelated to this LCD and are not subject to the DX criteria in this LCD. These codes were deleted to decrease provider confusion.)

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		M48.062 replaced the deleted M48.06.	
10/01/2016	R4	R4- This LCD has been updated to clarify that a repeat trial is not needed when replacing the stimulator due to the need for battery change, malfunction or end of stimulator life. Also deleted HCPCS code L8680 from Group 2	<ul style="list-style-type: none"> • Creation of Uniform LCDs Within a MAC Jurisdiction • Revisions Due To CPT/HCPCS Code Changes • Other (clarified that a repeat trial is not needed when replacing the stimulator due to the need for battery change, malfunction or end of stimulator life.)
10/01/2016	R3	<p>The LCD is revised to add new ICD-10 codes effective 10/1/2016: G57.73, T85.113A, T85.113D, T85.113S, T85.123A, T85.123D, T85.123S, T85.193A, T85.193D and T85.193S.</p> <p>The following ICD-10 codes descriptions were changed effective 10/1/2016: T85.112A, T85.112D, T85.112S, T85.122A, T85.122D, T85.122S, T85.192A, T85.192D and T85.192S.</p>	<ul style="list-style-type: none"> • Revisions Due To ICD-10-CM Code Changes
06/01/2016	R2	This LCD version was created as a result of DL35136 and DL36200 being released to a Final LCD. Multiple revisions to Indications & Limitations and Utilization Guidelines. Added multiple ICD-10 CM codes and deleted CPT code 95973 per 2016 CPT coding update.	<ul style="list-style-type: none"> • Creation of Uniform LCDs Within a MAC Jurisdiction
01/01/2016	R1	R1 CPT code 95973 was deleted from the Coverage Indication, Limitations and/or Medical Necessity and the Group 1 CPT/HCPCS Codes sections per 2016 CPT/HCPCS Code update	<ul style="list-style-type: none"> • Revisions Due To CPT/HCPCS Code Changes

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A57791 - Billing and Coding: Spinal Cord Stimulators for Chronic Pain

A54980 - Response to Comments: Spinal Cord Stimulators for Chronic Pain

LCD(s)

DL35136

- (MCD Archive Site)DL36200

- (MCD Archive Site)

Related National Coverage Documents

NCD(s)

160.7 - Electrical Nerve Stimulators

Public Version(s)

Updated on 01/29/2020 with effective dates 12/01/2019 - N/A

Updated on 01/29/2020 with effective dates 12/01/2019 - N/A

Updated on 11/20/2019 with effective dates 12/01/2019 - N/A

Updated on 08/22/2017 with effective dates 10/01/2017 - 11/30/2019

Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

Keywords

- spinal
- cord
- spinal cord
- stimulator
- SCS
- therapy
- neurostimulator
- implant
- trial