Local Coverage Determination (LCD): Peripheral Nerve Stimulation (L34328)

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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

LCD Title Peripheral Nerve Stimulation

Proposed LCD in Comment Period N/A

Source Proposed LCD DL34328

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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

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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

Peripheral nerve stimulation (PNS) may be covered for relief of chronic intractable pain for patients with conditions known to be responsive to this form of therapy, and only after attempts to cure the underlying conditions and appropriate attempts at medication management, physical therapy, psychological therapy and other less invasive interventional treatments. As with spinal nerve stimulations (spinal cord stimulators (SCS) are dealt with in a companion policy), severe neuropathic pain is typically well suited for successful responses to PNS. There may be rare selected situations where both spinal cord stimulators and peripheral neurostimulators are used together.

PNS refers to the placement of a lead by a physician (via open surgical or percutaneous approach) near the known anatomic location of a peripheral nerve. Peripheral nerve field stimulation (PNFS) refers to use of a lead placed to stimulate the subcutaneous distal distribution of an area of pain (indirectly stimulating the peripheral nerve). In both PNS and PNFS leads are composed of multiple contacts (of varying number) connected to an external pulse generator when temporary and implanted when made permanent.

PNS, like deep brain stimulation and spinal cord stimulation modulates the nervous system with electrical stimulation to lessen chronic pain and other conditions. PNFS has an uncertain mechanism of action.

PNS has been tried for over 50 years and has been used in a wide variety of chronic pain syndromes, but the scientific literature is limited for many of the indications tried. The most accepted uses of PNS involves one of two methods:

- Open exposure of a peripheral nerve and direct implantation of a PNS electrode (as in treatment of a radial nerve, sciatic nerve, median nerve, etc.).
- Percutaneous insertion of a PNS electrode in direct vicinity of the stimulated nerve (e.g., occipital nerve for severe headaches).

As with a SCS and PNS, performance of an effective trial is a pre-requisite of final implantation. Many experts recommend that the temporary neurostimulator be placed in an Ambulatory Surgical Center (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 for the proper surgery and follow up of the patient are available. Permanent neurostimulators must be placed in an ASC or hospital. Physicians performing PNS trials in place of service office must have like privileges at an ASC or hospital, or the physician must be board certified or board eligible in Pain Medicine, Orthopedic Surgery, or Neurosurgery by an ABMS Board or the equivalent as determined by the state of practice. Other ABMS Specialty Boards or the equivalent in the state of practice may be included if such practice is included in the training program curriculum.

It is preferable that the physicians performing the PNS trials will also perform the permanent implant. If the physician implanting the trial PNS does not or cannot implant the permanent neurostimulator(s), the patient should be informed of this in writing and given the name of the referral surgeon who will implant the permanent neurostimulator(s).

Coverage of PNS trials requires that patients have <u>all</u> of the following:

- Documented chronic and severe pain for at least 3 months,
- Documented failure of less invasive treatment modalities and medications,
- Lack of surgical contraindications including infections and medical risks,
- Appropriate proper patient education, discussion and disclosure of risks and benefits,
- No active substance abuse issues,
- Formal psychological screening by a mental health professional, and
- Successful stimulation trial with greater than or equal to 50% reduction in pain intensity before permanent implantation.

The only reliable predictor of PNS effectiveness is a trial of stimulation with implanted PNS electrodes. If a trial fails, a repeat trial is usually not appropriate unless there are extenuating circumstances that led to the trial failure (equipment malfunction, early lead migration, etc.), technological advances, or an alternative neuromodulary technique that may lead to a more successful second trial. Documentation must explain these unusual situations. It is expected that accurate patient selection will lead to most patients going on to receive permanent implants. 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.

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 imaging demonstrating proper lead placement, and the medical necessity of the trials. Failure to provide this documentation will be cause for postpayment 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.

Examples of peripheral stimulation indications with evidence of efficacy that may be covered are:

- PNS of occipital nerves for occipital neuralgia, post-surgical neuropathic pain, cervicogenic headaches and treatment resistant migraines.
- PNS of trigeminal nerves (and branches) for post-traumatic and post-surgical neuropathic pain in the face related to the trigeminal nerves.
- PNS of nerves in upper and lower extremities of complex regional pain syndromes (type 1 and 2), pain due to peripheral nerve injury, post-surgical scar formation, nerve entrapment, painful mononeuropathy, and painful amputation neuromas.
- PNS of intercostal and ilio-inguinal nerves for post-surgical and post-traumatic neuropathic pain involving these nerve distributions.

Current peer-reviewed data DOES NOT SUPPORT PNS for fibromyalgia, phantom limb pain, diffuse polyneuropathy, nociceptive pain in trunk or lower back, or angina pectoris. Claims for these indications will be denied as not reasonable and necessary. Current peer-reviewed data also is insufficient to warrant the medical necessity of coverage for PNFS for any condition. Therefore, this service will not be covered for any condition.

Summary of Evidence

General Information

Associated Information

Utilization Guidelines

Noridian expects no more than two services of 64555-(Percutaneous implantation of neurostimulator electrodes; peripheral nerve [excludes sacral nerve]) be billed per 365 days.

Trials will be limited to four leads with maximum of 16 contacts.

Sources of Information

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Bibliography

NA

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
12/01/2019	R10	The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD. 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.	 Other (The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.)
12/01/2019	R9	As required by CR 10901, all billing and coding information has been moved to the companion article; this article is linked to the LCD. 12/01/19: 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.	Revisions Due To Code Removal
01/01/2019	R8	The LCD revised to remove deleted CPT code 64550 from Group 1 effective 1/1/2019. 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. The draft LCD was issued prior to the implementation of the 21st Century Cures Act so the requirement of the Act does not apply to this policy.	Revisions Due To CPT/HCPCS Code Changes
11/02/2018	R7	08/23/2018 - 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. The draft LCD was issued prior to the implementation of the 21st Century Cures Act so the requirement of the Act does not apply to this policy. This LCD is being republished with a new Notice Period and Effective Date because the 45-day notice of the original Draft to Final LCD did not get published per CMS	 Other (No Notice Period article posted with original Draft to Final LCD in error.)

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		requirements.	
08/27/2018	R6	06/20/18 - 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. This Draft to Final LCD is new for Jurisdiction E Part A and was combined to include the Part A contract numbers in the existing policy in Jurisdiction E Part B and is effective 08/27/2018 for both Part A and Part B LCD also undated to	 Creation of Uniform LCDs Within a MAC Jurisdiction
		add ICD-10-CM code M54.81.	
01/01/2017	R5	LCD updated to remove $CPT^{(R)}$ codes 95974 and 95975 as these codes are also used in NCD 160.18 for Vagus Nerve Stimulation effective 10/01/2015.	 Reconsideration Request
01/01/2017	R4	0282T 0283T 0284T & 0285T deleted effective 12/31/2016. LCD revised to instruct providers effective January 1, 2017, providers are to use CPT [®] Code 64999 for both the trial and permanent insertion of the electrode array when billing for the procedures associated with either Peripheral Subcutaneous Field Stimulation or Peripheral Nerve Field Stimulation. Please place the respective procedure name in Loop 2400/SV101-7 for electronic claims or Item 19 on the CMS-1500 paper claim form. 64999 for these purposes is limited to one trial and one permanent insertion per a rolling 12 month period.	 Revisions Due To CPT/HCPCS Code Changes
10/01/2016	R3	Effective dates of service on or after 08/29/2016, As noted in CPT, 0282T <i>must</i> be billed when billing for a trial implantation of the leads not 64555in the Group 1 paragraph Added ICD-10-CM codes G56.43 and G57.73 effective 10/01/2016	 Other (Editorial change to Paragraph 1) Revisions Due To ICD-10-CM Code Changes
01/01/2016	R2	12/11/2015 - The following CPT/HCPCS codes were deleted:95973 was deleted from Group 1 per admin.	 Revisions Due To CPT/HCPCS Code Changes
10/01/2015	R1	The LCD revised for the CPT/HCPCS code update for 95972 descriptor only.	Other (The LCD revised for the

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
			CPT/HCPCS code update for 95972 descriptor only.)

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A55530 - Billing and Coding: Peripheral Nerve Stimulation

A56041 - Response to Comments: Peripheral Nerve Stimulation

LCD(s)

DL34328

- (MCD Archive Site)

Related National Coverage Documents

N/A

Public Version(s)

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 12/19/2018 with effective dates 01/01/2019 - 11/30/2019 Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

Keywords

- Peripheral Nerve
- Stimulation
- Trial