Local Coverage Determination (LCD): Peripheral Nerve Stimulation (L37360)

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
Noridian Healthcare Solutions, LLC	A and B MAC	02101 - MAC A	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02102 - MAC B	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02201 - MAC A	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02202 - MAC B	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02301 - MAC A	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02302 - MAC B	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02401 - MAC A	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	02402 - MAC B	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	03101 - MAC A	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03102 - MAC B	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03201 - MAC A	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03202 - MAC B	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03301 - MAC A	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03302 - MAC B	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03401 - MAC A	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03402 - MAC B	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03501 - MAC A	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03502 - MAC B	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03601 - MAC A	J - F	Wyoming
Noridian Healthcare Solutions, LLC	A and B MAC	03602 - MAC B	J - F	Wyoming

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LCD Information

Document Information

Original Effective Date
For services performed on or after 08/27/2018

Revision Effective Date

For services performed on or after 11/02/2018

Revision Ending Date
N/A

LCD ID
L37360

Retirement Date
N/A

LCD Title
Peripheral Nerve Stimulation

Notice Period Start Date
09/17/2018

Proposed LCD in Comment Period
N/A

Notice Period End Date
11/01/2018

Source Proposed LCD
DL37360

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."

Title XVIII of the Social Security Act, §1833(e). Prohibits Medicare payment for any claim lacking the necessary documentation to process the claim.

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 interdenominational treatments. As with spinal nerve stimulations (SCS 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 Spinal Cord Stimulator (SCS) and peripheral nerve stimulation (PNS), performance of an effective trial is a pre-requisite of final implantation. 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 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 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.

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

NA

Analysis of Evidence
(Rationale for Determination)

NA

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Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

999x Not Applicable

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

99999 Not Applicable

CPT/HCPCS Codes
Group 1 Paragraph:

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. 64999 for these purposes is not covered due to insufficient peer reviewed data to warrant the medical necessity of coverage.

Group 1 Codes:

61885	INSERTION OR REPLACEMENT OF CRANIAL NEUROSTIMULATOR PULSE GENERATOR OR RECEIVER, DIRECT OR INDUCTIVE COUPLING; WITH CONNECTION TO A SINGLE ELECTRODE ARRAY
64550	APPLICATION OF SURFACE (TRANSCUTANEOUS) NEUROSTIMULATOR (EG, TENS UNIT)
64553	PERCUTANEOUS IMPLANTATION OF NEUROSTIMULATOR ELECTRODE ARRAY; CRANIAL NERVE
64555	PERCUTANEOUS IMPLANTATION OF NEUROSTIMULATOR ELECTRODE ARRAY; PERIPHERAL NERVE (EXCLUDES SACRAL NERVE)
64561	PERCUTANEOUS IMPLANTATION OF NEUROSTIMULATOR ELECTRODE ARRAY; SACRAL NERVE (TRANSFORAMINAL PLACEMENT) INCLUDING IMAGE GUIDANCE, IF PERFORMED
64569	REVISION OR REPLACEMENT OF CRANIAL NERVE (EG, VAGUS NERVE) NEUROSTIMULATOR ELECTRODE ARRAY, INCLUDING CONNECTION TO EXISTING PULSE GENERATOR
64570	REMOVAL OF CRANIAL NERVE (EG, VAGUS NERVE) NEUROSTIMULATOR ELECTRODE ARRAY AND PULSE GENERATOR
64575	INCISION FOR IMPLANTATION OF NEUROSTIMULATOR ELECTRODE ARRAY; PERIPHERAL NERVE (EXCLUDES SACRAL NERVE)
64581	INCISION FOR IMPLANTATION OF NEUROSTIMULATOR ELECTRODE ARRAY; SACRAL NERVE (TRANSFORAMINAL PLACEMENT)
64585	REVISION OR REMOVAL OF PERIPHERAL NEUROSTIMULATOR ELECTRODE ARRAY
64590	INSERTION OR REPLACEMENT OF PERIPHERAL OR GASTRIC NEUROSTIMULATOR PULSE GENERATOR OR RECEIVER, DIRECT OR INDUCTIVE COUPLING
64595	REVISION OR REMOVAL OF PERIPHERAL OR GASTRIC NEUROSTIMULATOR PULSE GENERATOR OR RECEIVER
64999	UNLISTED PROCEDURE, NERVOUS SYSTEM

ICD-10 Codes that Support Medical Necessity
Group 1 Paragraph:

Group 1 codes do not apply to CPT® code 64585 for the purposes of this policy.

Group 1 Codes:

ICD-10 Codes	Description
B02.0	Zoster encephalitis
B02.22	Postherpetic trigeminal neuralgia
B02.23	Postherpetic polyneuropathy
B02.29	Other postherpetic nervous system involvement
E08.41	Diabetes mellitus due to underlying condition with diabetic mononeuropathy
E09.41	Drug or chemical induced diabetes mellitus with neurological complications with diabetic mononeuropathy
E10.41	Type 1 diabetes mellitus with diabetic mononeuropathy
E11.41	Type 2 diabetes mellitus with diabetic mononeuropathy
E13.41	Other specified diabetes mellitus with diabetic mononeuropathy
G43.011	Migraine without aura, intractable, with status migrainosus
G43.019	Migraine without aura, intractable, without status migrainosus
G43.111	Migraine with aura, intractable, with status migrainosus
G43.A1	Cyclical vomiting, intractable
G43.B1	Ophthalmoplegic migraine, intractable
G43.C1	Periodic headache syndromes in child or adult, intractable
G43.D1	Abdominal migraine, intractable
G43.811	Other migraine, intractable, with status migrainosus
G43.819	Other migraine, intractable, without status migrainosus
G44.021	Chronic cluster headache, intractable
G44.029	Chronic cluster headache, not intractable

ICD-10 Codes	Description
G44.321	Chronic post-traumatic headache, intractable
G44.329	Chronic post-traumatic headache, not intractable
G44.59	Other complicated headache syndrome
G50.0	Trigeminal neuralgia
G54.1	Lumbosacral plexus disorders
G54.2	Cervical root disorders, not elsewhere classified
G54.3	Thoracic root disorders, not elsewhere classified
G54.4	Lumbosacral root disorders, not elsewhere classified
G54.8	Other nerve root and plexus disorders
G54.9	Nerve root and plexus disorder, unspecified
G55	Nerve root and plexus compressions in diseases classified elsewhere
G56.41	Causalgia of right upper limb
G56.42	Causalgia of left upper limb
G56.43	Causalgia of bilateral upper limbs
G57.71	Causalgia of right lower limb
G57.72	Causalgia of left lower limb
G57.73	Causalgia of bilateral lower limbs
G58.8	Other specified mononeuropathies
G58.9	Mononeuropathy, unspecified
G59	Mononeuropathy in diseases classified elsewhere
G89.22	Chronic post-thoracotomy pain
G90.50	Complex regional pain syndrome I, unspecified
G90.511	Complex regional pain syndrome I of right upper limb
G90.512	Complex regional pain syndrome I of left upper limb
G90.513	Complex regional pain syndrome I of upper limb, bilateral
G90.521	Complex regional pain syndrome I of right lower limb
G90.522	Complex regional pain syndrome I of left lower limb
G90.523	Complex regional pain syndrome I of lower limb, bilateral
G90.59	Complex regional pain syndrome I of other specified site
M54.81	Occipital neuralgia

ICD-10 Codes that DO NOT Support Medical Necessity
Group 1 Paragraph: All diagnoses not listed in the ICD-10-CM Codes That Support Medical Necessity" section of this LCD.

Group 1 Codes: N/A

ICD-10 Additional Information Back to Top

General Information

Associated Information

Documentation Requirement

The patient's medical record must contain documentation that fully supports the medical necessity for services included within this LCD. (Please see "Coverage Indications, Limitations and/or Medical Necessity.") This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

The clinical record should include elements leading to the diagnosis and the therapies tried before the decision to use PNS. When the documentation does not meet the criteria for the service rendered or the documentation does

not establish the medical necessity for the service, such services will be denied as not reasonable and necessary.

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.

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.

LCD updated to add ICD-10-CM code M54.81.

Sources of Information

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9. Occipital Nerve Stimulation. Blue Cross Blue Shield of Vermont. July, 2011.

Bibliography

NA

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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
11/02/2018	R1	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.	• 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
		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 requirements.	

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Associated Documents

Attachments N/A

Related Local Coverage Documents Article(s) A55531 - Noncoverage of Peripheral Nerve Field Stimulation – Coding and Billing A56042 - Response to Comments: Peripheral Nerve Stimulation LCD(s) DL37360 - Peripheral Nerve Stimulation

Related National Coverage Documents N/A

Public Version(s) Updated on 08/30/2018 with effective dates 11/02/2018 - N/A Updated on 06/25/2018 with effective dates 08/27/2018 - N/A Back to Top

Keywords

- Peripheral Nerve
- Stimulation
- Trial
- 61885
- 64550
- 64553
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