Peripheral Nerve Stimulation

Noridian Healthcare Solutions, LLC

Please Note: This is a Proposed LCD.
Proposed LCDs are works in progress and not necessarily a reflection of the current policies or practices. Proposed LCDs in an approval status display on the CMS MCD for public review.

Contractor Information

<table>
<thead>
<tr>
<th>Contractor Name</th>
<th>Noridian Healthcare Solutions, LLC</th>
</tr>
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<tbody>
<tr>
<td>Contract Number</td>
<td>03102</td>
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<tr>
<td>Contract Type</td>
<td>A and B MAC</td>
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Proposed LCD Information
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<td>Proposed LCD Version</td>
<td>5</td>
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<tr>
<td>Proposed LCD Title</td>
<td>Peripheral Nerve Stimulation</td>
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<td>AMA CPT</td>
<td>CPT only copyright 2002-2017 American Medical Association. All rights reserved.</td>
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<tr>
<td>ADA CDT</td>
<td>CDT only copyright 2016 American Dental Association. All rights reserved.</td>
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<td>AHA NUBC Copyright Statements</td>
<td>UB-04 Manual. OFFICIAL UB-04 DATA SPECIFICATIONS MANUAL, 2014, is copyrighted by American Hospital Association (&quot;AHA&quot;), Chicago, Illinois. No portion of OFFICIAL UB-04 MANUAL may be reproduced, sorted in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, without prior express, written consent of AHA. Health Forum reserves the right to change the copyright notice from time to time upon written notice to Company.</td>
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<tr>
<td>CMS National Coverage Policy</td>
<td>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.”</td>
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<td>Super MAC Jurisdiction</td>
<td>J - F</td>
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<td>Coverage Guidance</td>
<td>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,</td>
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psychological therapy and other less invasive interventional 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 all 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.

**Proposed Process Information**

**Synopsis of Changes**

Not Applicable

**Fields Changed**

- Proposed

**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.


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<th>Meeting Date</th>
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<td>Noridian Healthcare Solutions Room W3 900 42nd Street S Fargo, ND 58108-6704</td>
<td>Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming</td>
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Comment Period Start Date 06/01/2017
Comment Period End Date 08/14/2017
Released to Final LCD Date Not yet released.
Reason(s) for Proposed LCD Creation of Uniform LCDs Within a MAC Jurisdiction
Noridian Healthcare Solutions, LLC JF Part B Contractor Medical Director(s)
Proposed LCD Contact Attention: Draft LCD Comments
PO Box 6781
Fargo, North Dakota 58108-6781
policydraft@noridian.com

Coding Information

Bill Type Codes 999x Not Applicable
Revenue Codes 99999 Not Applicable

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

CPT/HCPCS 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

64553 PERCUTANEOUS IMPLANTATION OF NEUROSTIMULATOR ELECTRODE ARRAY; CRANIAL NERVE

64555 PERCUTANEOUS IMPLANTATION OF NEUROSTIMULATOR ELECTRODE ARRAY; PERIPHERAL NERVE (EXCLUDES SACRAL NERVE)
PERCUTANEOUS IMPLANTATION OF NEUROSTIMULATOR ELECTRODE ARRAY;
SACRAL NERVE (TRANSFORAMINAL PLACEMENT) INCLUDING IMAGE GUIDANCE, IF PERFORMED

64561

REVISION OR REPLACEMENT OF CRANIAL NERVE (EG, VAGUS NERVE) NEUROSTIMULATOR ELECTRODE ARRAY, INCLUDING CONNECTION TO EXISTING PULSE GENERATOR

64569

REMOVAL OF CRANIAL NERVE (EG, VAGUS NERVE) NEUROSTIMULATOR ELECTRODE ARRAY AND PULSE GENERATOR

64570

INCISION FOR IMPLANTATION OF NEUROSTIMULATOR ELECTRODE ARRAY;
PERIPHERAL NERVE (EXCLUDES SACRAL NERVE)

64575

INCISION FOR IMPLANTATION OF NEUROSTIMULATOR ELECTRODE ARRAY;
SACRAL NERVE (TRANSFORAMINAL PLACEMENT)

64581

REVISON OR REMOVAL OF PERIPHERAL NEUROSTIMULATOR ELECTRODE ARRAY INSERTION OR REPLACEMENT OF PERIPHERAL OR GASTRIC NEUROSTIMULATOR PULSE GENERATOR OR RECEIVER, DIRECT OR INDUCTIVE COUPLING

64590

REVISON OR REMOVAL OF PERIPHERAL OR GASTRIC NEUROSTIMULATOR PULSE GENERATOR OR RECEIVER

64595

UNLISTED PROCEDURE, NERVOUS SYSTEM

64999

Does the CPT 30% Coding Rule Apply? No

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

Group 1: Codes
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

Note: Performance is optimized by using code ranges.
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
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

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**

**Note: Performance is optimized by using code ranges.**

Additional ICD-10 Information

Associated Documents

**Proposed**

**Attachments**
There are no attachments for this LCD.

**Related Local Coverage Documents**
This LCD version has no Related Local Coverage Documents.

**Related National Coverage Documents**
This LCD version has no Related National Coverage Documents.