

Posterior Tibial Nerve Stimulation (PTNS) for Urinary Control

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



Contractor Name Noridian Healthcare Solutions, LLC

Contract Number 01112

Contract Type A and B MAC

Associated Contract Numbers (A and B MAC - 01182 - J - E) Noridian Healthcare Solutions, LLC, (A and B MAC - 01212 - J - E) Noridian Healthcare Solutions, LLC, (A and B MAC - 01312 - J - E) Noridian Healthcare Solutions, LLC

Proposed LCD Information



Source LCD ID L34226

Proposed LCD ID DL34226

Original ICD-9 LCD ID N/A

Proposed LCD Version 5

Proposed LCD Title Posterior Tibial Nerve Stimulation (PTNS) for Urinary Control

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Title XVIII of the Social Security Act, Section 1862(a)(1)(A) allows coverage and payment for items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member.

**CMS National
Coverage
Policy**

Title XVIII of the Social Security Act, §1862(a)(7) and 42 Code of Federal Regulations, §411.15 et seq. These citations exclude routine physical examinations.

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

Jurisdiction California - Northern
**Super MAC
Jurisdiction** J - E

Coverage Guidance



Coverage Posterior Tibial Nerve Stimulation (PTNS), a minimally invasive procedure,
Indications, consists of insertion of an acupuncture needle above the medial malleolus into a
Limitations superficial branch of the posterior tibial nerve. An adjustable low voltage

**and/or
Medical
Necessity**

electrical impulse (10mA, 1-10 Hz frequency) travels via the posterior tibial nerve to the sacral nerve plexus to alter pelvic floor function by neuromodulation.

Posterior Tibial Nerve Stimulation (PTNS) is a minimally invasive neuromodulation system designed to deliver retrograde electrical stimulation to the sacral nerve plexus through percutaneous electrical stimulation of the posterior tibial nerve. Noridian has determined that PTNS will be covered for treatment of urinary urgency, urinary frequency, and urge incontinence. This article **does not** address the following NCD: CMS Internet Only Manual (IOM) *Medicare National Coverage Determination (NCD) Manual*, Publication 100-03, Section 230.16 *Bladder Stimulators (Pacemakers) Not Covered* at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part4.pdf. Noridian covers Sacral Nerve Stimulation with restrictions in a separate coverage article.

PTNS Procedure Description

The posterior tibial nerve contains mixed sensory motor nerve fibers that originate from L4 through S3, which modulate the innervation to the bladder, urinary sphincter, and pelvic floor. The specific mechanism of action of neuromodulation is unclear, although theories include improved blood flow and change in neurochemical balance along the neurons. Neuromodulation may have a direct effect on the detrusor or a central effect on the micturition centers of the brain.

Using a battery-powered, handheld stimulator and a 34-gauge needle electrode, one can access and stimulate the tibial nerve. Patients receive a 30-minute weekly treatment in the office for 12 weeks. Patients treated with PTNS may begin to see changes in their voiding patterns after four to six treatments, with nocturia and urge incontinence decreases usually reported first. Patients who respond to the treatment require additional therapy at individually defined treatment intervals for sustained relief of symptoms.

Coverage Guidelines

Consistent with Noridian, manufacturer instructions, and existing literature descriptions of appropriate clinical usage, Noridian expects this treatment to be (generally) delivered in an office setting (Place of Service 11) and that the standard treatment regimen will consist of 30-minute sessions given weekly for 12 weeks.

Coverage for initial therapy must document failed standard anticholinergic drug therapy or that the patient demonstrates intolerance to the anticholinergic drug therapy despite best attempts at management of the most common side effects of such therapy, such as dry mouth and constipation.

Coverage for maintenance therapy on an every-three-weeks basis for up to two

years can be extended to patients who demonstrate significant improvement in overactive bladder (OAB) symptoms at the end of the standard 12-week course of therapy. Documentation must support the initial improvement and the need for the additional treatments.

Bill no more than three Evaluation and Management (E&M) services during any initial course of PTNS treatment:

1. On the initial visit
2. At the 5th or 6th visit to assess progress
3. At the end of the initial 12-week course of therapy

The patient's medical record must contain adequate documentation identifying the CPT and ICD-10-CM coding, and the need for and level of these visits. Noridian reminds the provider community that this coverage decision may be modified or terminated depending upon future literature or clinical experience and usage.

Proposed Process Information



The medical record must indicate the patient has the cognitive ability to navigate to appropriate facilities for voiding.

Supported documentation evidencing the condition and treatment is expected to be documented in the medical record and be available upon request.

The medical record must document at least one of the following criteria:

- Patient failed treatment with two anticholinergic drugs, each taken for at least 4 weeks duration, prior to the PTNS therapy initiation,
- Patient intolerance to anticholinergic drug therapy. To validate intolerance, the medical record must document the specific medical management used to address dry mouth and constipation, the most common side effects of this therapy.

Associated Information

The following additional documentation is also required:

- Overactive bladder symptoms (OAB)
- Failed alternative therapy
- Measurable improvement of symptoms after the 12, 30-minute weekly treatments

- Continued improvement for every three week maintenance therapy

There is no evidence to support continued PTNS therapy after two years of treatment at this time.

The development and coverage guidelines in this policy were based on a review of pertinent medical literature, policies from other Medicare contractors, and discussions with appropriate specialists.

MacDiarmid SA, Peters SM, Shobeiri SA, Wooldridge LS, Rovner ES, Leong FC, et al. Long Term Durability of Percutaneous Tibial Nerve Stimulation for the Treatment of Overactive Bladder. *Journal of Urology*. Jan 2010;183:234-40.

Peters KM, Carrico DJ, Perez-Marrero RA, Khan AU, Wooldridge LS, Davis LG, et al. Randomized Trial of Percutaneous Tibial Nerve Stimulation Versus Sham Efficacy in the Treatment of Overactive Bladder Syndrome: Results from the SUmIT Trial. *Journal of Urology*. Apr 2010;183:1438-43.

Sources of Information and Basis for Decision

Peters KM, MacDiarmid SA, Wooldridge LS, Leong FC, Shobeiri SA, Rovner ES, et al. Randomized Trial of Percutaneous Tibial Nerve Stimulation Versus Extended-Release Tolterodine: Results from the Overactive Bladder Innovative Therapy Trial. *Journal of Urology*. Sep 2009;182:1055-61.

Updated Sources:

Peters KM, Carrico DJ, MacDiarmid SA, et al. Sustained Therapeutic Effects of Percutaneous Tibial Nerve Stimulation: 24-month Results of the STEP Study. *Neurourology and Urodynamics*. Apr 2012, DOI 10.1002/nau.22266.

Gormley EA, Lightner DJ, Burgiom KL, et al. AUA Guideline Diagnosis and Treatment of Overactive Bladder (non-Neurogenic) in Adults: AUA/SUFU Guideline, May 2012.

	Meeting Date	Meeting Information	State
Open Meetings	10/01/2015	The open public meeting will be held at the following location: Embassy Suites Flamingo Ballroom 4315 Swenson St. Las Vegas, NV 89119	American Samoa, California - Entire State, Guam, Hawaii, Northern Mariana Islands, California - Northern, California - Southern

	Meeting Date	Meeting Information	State
Part B MAC Contractor Advisory Committee (CAC) Meetings	10/09/2015	The Pacific Club, Card Room 1451 Queen Emma St Honolulu, HI 96813	American Samoa, Guam, Hawaii, Northern Mariana Islands
	10/21/2015	DoubleTree by Hilton San Francisco Airport Tiburon/Sausalito Room 835 Airport Boulevard Burlingame, CA 94010	California - Entire State, California - Northern, California - Southern
	10/22/2015	Clark County Medical Association/NV State Medical Association 2590 E Russell Rd Las Vegas, NV 89120	Nevada

Comment Period Start Date 10/01/2015
Comment Period End Date 12/07/2015
Released to Final LCD Date Not yet released.

Reason for Proposed LCD Creation of Uniform LCDs...
Creation of Uniform LCDs Within a MAC Jurisdiction

Proposed LCD Contact Noridian Healthcare Solutions, LLC JE Part B Contractor Medical Director(s)
Attention: Draft LCD Comments
PO Box 6783
Fargo, North Dakota 58108-6783
policyb.drafts@noridian.com

Coding Information



Bill Type Codes 013x Hospital Outpatient
071x Clinic - Rural Health
077x Clinic - Federally Qualified Health Center (FQHC)
085x Critical Access Hospital

Revenue Codes 99999 Not Applicable

CPT/HCPCS Codes **Group 1: Paragraph CPT Code**
Group 1: Codes

64566 POSTERIOR TIBIAL NEUROSTIMULATION,
PERCUTANEOUS NEEDLE ELECTRODE, SINGLE
TREATMENT, INCLUDES PROGRAMMING

**Does the CPT 30%
Coding Rule Apply?** No

Group 1: Paragraph

The following diagnoses codes support medical necessity:

Group 1: Codes

**ICD-10 Codes that
Support Medical
Necessity**

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

- N30.10 Interstitial cystitis (chronic) without hematuria
- N30.11 Interstitial cystitis (chronic) with hematuria
- N39.41 Urge incontinence
- N39.42 Incontinence without sensory awareness
- N39.46 Mixed incontinence
- N39.490 Overflow incontinence
- N39.498 Other specified urinary incontinence
- R32 Unspecified urinary incontinence
- R33.0 Drug induced retention of urine
- R33.8 Other retention of urine
- R33.9 Retention of urine, unspecified
- R35.0 Frequency of micturition
- R39.14 Feeling of incomplete bladder emptying
- R39.15 Urgency of urination

**ICD-10 Codes that DO
NOT Support Medical
Necessity**

Group 1: Paragraph

Group 1: Codes

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

**Additional ICD-10
Information**

Associated Documents



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.

**Version 5 - Updated on 08/06/2015 16:55:27, by
Christine.Burnside@noridian.com, with effective dates N/A - N/A
(Approved).**

[Version 4](#) - Updated on 08/06/2015 13:32:31, by
Ronda.Sears@noridian.com, with effective dates N/A - N/A.

All Versions

[Version 3](#) - Updated on 08/04/2015 14:19:06, by
Ronda.Sears@noridian.com, with effective dates N/A - N/A.

[Version 2](#) - Updated on 08/04/2015 13:41:45, by
Ronda.Sears@noridian.com, with effective dates N/A - N/A.

[Version 1](#) - Updated on 08/04/2015 13:25:32, by
Ronda.Sears@noridian.com, with effective dates 10/01/2015 - N/A.