Medical Policy

Percutaneous Tibial Nerve Stimulation

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Policy Number: 583
BCBSA Reference Number: 7.01.106
NCD/LCD: Local Coverage Determination (LCD): Posterior Tibial Nerve Stimulation for Voiding Dysfunction (L33396)

Related Policies
- Pelvic Floor Stimulation as a Treatment of Urinary Incontinence, #470
- Sacral Nerve Neuromodulation/Stimulation, #153
- Biofeedback as a Treatment of Urinary Incontinence, #173
- Transanal Radiofrequency Treatment of Fecal Incontinence, #309
- Biofeedback as a Treatment of Fecal Incontinence or Constipation, #308
- Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence, #471
- Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT), #172

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Percutaneous tibial nerve stimulation is considered INVESTIGATIONAL for all indications, including but not limited to the following:
- Urinary dysfunction, including but not limited to overactive bladder syndrome, neurogenic bladder, urinary frequency, urgency, incontinence, and retention
- Fecal incontinence.

Medicare HMO BlueSM and Medicare PPO BlueSM Members

National Government Services (NGS) will allow PTNS coverage for beneficiaries with overactive bladder syndrome (OBS) as a less invasive “third-line treatment” for selected patients who meet the criteria outlined in the AUA’s Guideline as listed below.

PTNS is considered reasonable and necessary for a beneficiary when the following criteria are met:
- An evaluation by an appropriate specialist, usually a urologist or urogynecologist, has been performed and the specialist has determined that the patient is a candidate for PTNS; and
The medical record documents that the beneficiary has a) been compliant with and failed a trial of symptom-appropriate behavioral therapy of sufficient length to evaluate potential efficacy and b) been compliant with and has failed or been unable to tolerate a trial of at least two appropriate medications administered for four (4) to eight (8) weeks; and

- The voiding diary shows continued findings of OBS; and
- The beneficiary has documented a willingness to attend in-office treatment sessions, to comply with the behavioral therapies, and to continue to keep voiding diaries including documentation of behavioral therapy compliance; and
- Treatment will consist of an initial course of one 30-minute session per week for 12 weeks.

Treatments for relapse shall only be allowed for those patients who achieve a >50% decrease in OBS symptoms with the initial treatment and then relapse.

Medical necessity criteria and coding guidance for Medicare Advantage members living in Massachusetts can be found through the link below.

Local Coverage Determination (LCD): Posterior Tibial Nerve Stimulation for Voiding Dysfunction (L33396)

For medical necessity criteria and coding guidance for Medicare Advantage members living outside of Massachusetts, please see the Centers for Medicare and Medicaid Services website for information regarding your specific jurisdiction at https://www.cms.gov.

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products.
See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th></th>
<th>Commercial Managed Care (HMO and POS)</th>
<th>Commercial PPO and Indemnity</th>
<th>Medicare HMO Blue&lt;sup&gt;SM&lt;/sup&gt;</th>
<th>Medicare PPO Blue&lt;sup&gt;SM&lt;/sup&gt;</th>
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<tbody>
<tr>
<td><strong>Outpatient</strong></td>
<td>This is not a covered service.</td>
<td>This is not a covered service.</td>
<td>No</td>
<td>No</td>
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CPT Codes / HCPCS Codes / ICD-9 Codes
Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The following CPT code is considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:
### CPT Codes

<table>
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<th>CPT codes</th>
<th>Code Description</th>
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<tr>
<td>64566</td>
<td>Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming</td>
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### Description

Altering the function of the posterior tibial nerve with PTNS is believed to improve voiding function and control. Although the posterior tibial nerve is located near the ankle, it is derived from the lumbar-sacral nerves (L4-S3), which control the bladder detrusor and perineal floor. Voiding dysfunction includes urinary frequency, urgency, incontinence, and nonobstructive retention. Common causes of voiding dysfunction are pelvic floor dysfunction (eg, from pregnancy, childbirth, surgery), inflammation, medication (eg, diuretics and anticholinergics), obesity, psychogenic factors, and disease (eg, multiple sclerosis, spinal cord injury, detrusor hyperreflexia, diabetes with peripheral nerve involvement). The current FDA-cleared indication for PTNS is overactive bladder (OAB), which is defined as the presence of urinary urgency, with or without urgency urinary incontinence that is usually accompanied by frequency and nocturia and is not associated with urinary tract infections or other known pathology.

The procedure for PTNS consists of the insertion of a needle above the medial malleolus into the posterior tibial nerve followed by the application of low-voltage (10 mA, 1-10 Hz frequency) electrical stimulation that produces sensory and motor responses (ie, a tickling sensation and plantar flexion or fanning of all toes). Noninvasive PTNS has also been delivered with surface electrodes. The recommended course of treatment is an initial series of 12 weekly office-based treatments followed by an individualized maintenance treatment schedule.

PTNS is less invasive than traditional sacral nerve neuromodulation (see Policy No. 7.01.69), which has been successfully used in the treatment of urinary dysfunction but requires implantation of a permanent device. In sacral root neuromodulation, an implantable pulse generator that delivers controlled electrical impulses is attached to wire leads that connect to the sacral nerves, most commonly the S3 nerve root that modulates the neural pathways controlling bladder function.

PTNS is not cleared by FDA for treating fecal incontinence; however, the treatment has been proposed for this purpose. The manufacturer recommends a course of treatment for fecal incontinence similar to the one used to treat OAB: an initial course of 12 weekly sessions of tibial nerve stimulation followed by a personalized schedule of follow-up treatments.

### Summary

Percutaneous tibial nerve stimulation (PTNS, also known as posterior tibial nerve stimulation) is a technique of electrical neuromodulation used primarily for treating voiding dysfunction. The available randomized controlled trials (RCTs) report short-term (up to 12 weeks) improvements on measures of urinary incontinence and overactive bladder. Up to 36 months of data are available for some patients enrolled in RCTs who responded to an initial course of treatment, but not on other RCT participants. There is a lack of control data beyond 12 weeks to control for a possible placebo response. Moreover, there is a high dropout rate in long-term follow-up. The optimal maintenance regimen after an initial 12-week course is unclear. Systematic reviews of the evidence have found short-term improvements with PTNS and have not identified long-term comparative studies. Clinical input obtained in 2012 was mixed regarding whether PTNS for voiding dysfunction should be considered medically necessary. In addition, there is insufficient evidence that PTNS is effective for other conditions such as fecal incontinence. Based on this evidence and clinical input, PTNS is considered investigational for all indications.

### Policy History

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<td>Date</td>
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<tr>
<td>6/2013</td>
<td>New references from BCBSA National medical policy.</td>
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<tr>
<td>1/19/2011</td>
<td>New policy, effective 1/19/2011, describing covered and non-covered indications.</td>
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### Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

- [Medical Policy Terms of Use](#)
- [Managed Care Guidelines](#)
- [Indemnity/PPO Guidelines](#)
- [Clinical Exception Process](#)
- [Medical Technology Assessment Guidelines](#)

### References


