

Clinical Policy: Posterior Tibial Nerve Stimulation for Voiding Dysfunction

Reference Number: PA.CP.MP.133

Plan Effective Date: 01/2018

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Description

Posterior tibial nerve stimulation (PTNS), also known as peripheral tibial nerve stimulation, is a minimally invasive form of electrical neuromodulation used to treat overactive bladder (OAB) syndrome and associated symptoms of urinary urgency, urinary frequency, and urge urinary incontinence.¹ This policy describes the medical necessity requirements for posterior tibial nerve stimulation.

Policy/Criteria

- I. It is the policy of PA Health and Wellness[®] (PHW) that posterior tibial nerve stimulation (PTNS) is medically necessary when all of the following criteria are met:
 - A. Diagnosis of overactive bladder (OAB);
 - B. There has been a failure of conservative medical management (e.g. behavioral therapies such as bladder training or pelvic floor muscle training, or pharmacotherapy with oral medications used with the intent to treat OAB), unless conservative management is not desired or is medically contraindicated;
 - C. Service is provided in accordance with the standard treatment regimen of 30-minute weekly sessions for 12 weeks.
- II. It is the policy of PHW that once-a-month maintenance treatments with PTNS **are medically necessary** for patients who experience significant improvement in their OAB symptoms after the 12 initial treatments. Treatment frequency may vary depending on return of symptoms.
- III. It is the policy of PHW that there is insufficient evidence to support the use of PTNS beyond 12 months or when there is no improvement in urinary dysfunction.
- IV. It is the policy of PHW that there is insufficient evidence in the published peer-reviewed literature to support the use of implantable tibial nerve stimulation for the treatment of urinary voiding dysfunction.

Background

The term "voiding dysfunction" has been used to refer to urinary incontinence, urinary retention, and symptoms of frequency and urgency. Overactive bladder (OAB) is a specific type of voiding dysfunction that includes any of the following symptoms: urinary frequency, urinary urgency, urge incontinence, and nocturia.² OAB can significantly impact quality of life including physical function, sexual function, and social interactions. Treatments for OAB include lifestyle changes, bladder training, pelvic floor muscle training and anticholinergic (anti-muscarinic) drugs.³

Posterior tibial nerve stimulation (PTNS) involves indirect modulation of the specific nerve that controls bladder function (i.e., the sacral nerve plexus) via stimulation of the posterior tibial nerve accessed just above the ankle. This minimally invasive form of neuromodulation consists of insertion of a 34-gauge needle electrode approximately five centimeters (cm) cephalad to the

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medial malleolus and two cm posterior to the tibia near the tibial nerve. A surface electrode is placed on the medial aspect of the foot. The needle electrode is connected via a lead wire to a low-voltage electrical stimulator. Stimulation is administered at a current level of 0.5 to nine milliamperes (mA) at 20 hertz (Hz) and continues for 30 minutes. Initial treatment regimens typically consist of 12 weekly sessions, with responders exhibiting some symptom improvement after six to eight sessions. Maintenance treatment sessions may be required to sustain the response to treatment.⁴

Several implantable tibial nerve neuromodulation systems, including a battery-less leadless, miniature implantable device, are currently under investigation for the management of OAB, however, evidence is still limited on their benefits and efficacy at this time.

National Institute for Health and Care Excellence (NICE)

According to NICE, current evidence demonstrates that PTNS for OAB syndrome is effective in reducing symptoms in the short term and medium term. Per NICE guidance, PTNS for OAB syndrome does not have major safety concerns, and the use of this procedure should with standard protocols for consent, audit, and clinical governance.³

A NICE guidance on urinary incontinence in women does not recommend the “routine” use of PTNS to treat OAB. Rather, they recommend PTNS for OAB for following:

- There has been a multidisciplinary team (MDT) review, and
- Conservative management including OAB drug treatment has not worked adequately, and
- The woman does not want botulinum toxin A or percutaneous sacral nerve stimulation.¹⁰

American Urological Association

Clinicians may offer PTNS as third-line treatment in a carefully selected patient population, characterized by moderately severe baseline incontinence and frequency and willingness to comply with the PTNS protocol. Patients must also have the resources to make frequent office visits both during the initial treatment phase and to obtain maintenance treatments in order to achieve and maintain treatment effects. The most common protocol is the application of 30 minutes of stimulation once a week for 12 weeks (the trial duration; for continued benefit, weekly stimulation would have to continue).¹

Studies to date evaluating PTNS for the treatment of OAB conclude there is evidence of benefit, although most studies have been small and report short-term outcomes after 12 weeks of treatment. A small study of 33 PTNS responders who continued therapy for six to 12 months reported excellent durability through 12 months.⁵ Another small study reported sustained safety and efficacy of PTNS for the treatment of OAB symptom control over 24 months with initial success after 12 weekly treatments, followed by a 14-week prescribed tapering protocol and a personalized treatment plan with an average of 1.3 treatments per month.⁶

Coding Implications

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from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT codes that support medical necessity

CPT® Codes	Description
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming

CPT codes that do not support medical necessity

CPT® Codes	Description
0587T	Percutaneous implantation or replacement of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming and imaging guidance when performed, posterior tibial nerve
0588T	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve
0589T	Electronic analysis with simple programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, posterior tibial nerve, 1-3 parameters
0590T	Electronic analysis with complex programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, posterior tibial nerve, 4 or more parameters

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Background updated. References reviewed and updated.	09/18	
Revised I.B, examples of pharmacotherapy, to include oral anti-muscarinics or β 3-adrenoceptor agonists. References reviewed and updated. Specialist review.	12/19	
Added to the policy criteria that implantable tibial nerve stimulation is investigational. Added the following CPT codes as investigational: 0587T, 0588T, 0589T and 0590T References reviewed and updated. Specialist review.	06/2021	
Annual review. Replaced “investigational” language with “insufficient evidence to support.” References reviewed, reformatted and updated.	07/26/2022	

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Changed “review date” in the header to “date of last revision” and “date” in the revision log header to “revision date.” Replaced member with member/enrollee. Specialist review.		
Annual review. Revised Criteria I.B. to include examples of behavioral therapies such as bladder training or pelvic floor muscle training. Background updated to with no impact on criteria. Dashes removed from code ranges. References reviewed and updated. Annual review. Revised policy statement and all criteria verbiage in criteria I. ICD-10 CM Diagnosis Code table removed. References reviewed and updated. Reviewed by external specialist.	09/2023	12/8/2023
Annual review. Updated criteria under I.B. by replacing anti-muscarinics or β3-adrenoceptor agonists and/or antibiotics for urinary tract infections with medications used with the intent to treat OAB. References reviewed and updated.	07/2024	

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