

**EFFECTIVE DATE:** 09|01|2018

**POLICY LAST UPDATED:** 06|05|2018

## OVERVIEW

Percutaneous tibial nerve stimulation (PTNS); also known as posterior tibial nerve stimulation) is a technique of electrical neuromodulation used primarily for treating voiding dysfunction.

## MEDICAL CRITERIA

PTNS is considered reasonable and necessary 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 overactive bladder syndrome (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.

## PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare and recommended for Commercial products and obtained via the online tool for participating providers. See the Related Policies section.

## POLICY STATEMENT

### BlueCHiP for Medicare and Commercial Products

PTNS for overactive bladder syndrome is covered when the medical criteria are met.

### BlueCHiP for Medicare and Commercial Products

Percutaneous tibial nerve stimulator to treat fecal incontinence is investigational and therefore, a contract exclusion as it is not U.S. Food and Drug Administration (FDA) cleared for this indication.

## COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable coverage for surgery.

## BACKGROUND

Common causes of voiding dysfunction are pelvic floor neuromuscular changes (eg, from pregnancy, childbirth, surgery), inflammation, medication (eg, diuretics, anticholinergics), obesity, psychogenic factors, and disease (e.g., multiple sclerosis, spinal cord injury, detrusor hyperreflexia, diabetes with peripheral nerve involvement).

Altering the function of the posterior tibial nerve with percutaneous tibial nerve stimulation (PTNS) is believed to improve voiding function and control. The mechanism of action is believed to be retrograde stimulation of the lumbosacral nerves (L4-S3) via the posterior tibial nerve located near the ankle. The lumbosacral nerves control the bladder detrusor and perineal floor. Overactive bladder is voiding dysfunction that is characterized by urinary frequency, urgency, urge incontinence, and nonobstructive retention.

Approaches to the treatment of incontinence differentiate between urge incontinence and stress incontinence. Conservative behavioral management such as lifestyle modification (eg, dietary changes, weight reduction, fluid management, smoking cessation) along with pelvic floor exercises and bladder training are part of the initial treatment of overactive bladder symptoms and both types of incontinence. Pharmacotherapy is another option, and different medications target different symptoms. Some individuals experience mixed incontinence.

The current indication cleared by the U.S. Food and Drug Administration (FDA) for PTNS is overactive bladder and associated symptoms of urinary frequency, urinary urgency, and urge incontinence. 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 as evidenced by a tickling sensation and plantar flexion or fanning of all toes. Noninvasive PTNS has also been delivered with transcutaneous or 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 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 has been proposed as a treatment for non-neurogenic and neurogenic bladder syndromes and fecal incontinence.

In July 2005, the Urgent® PC Neuromodulation System was the initial device cleared for marketing by FDA through the 510(k) process for PTNS to treat patients suffering from urinary urgency, urinary frequency, and urge incontinence. The Urgent® PC Neuromodulation System and NURO™ Neuromodulation System are not FDA-cleared for other indications, such as the treatment of fecal incontinence. Therefore, this is considered a contract exclusion for BlueCHiP for Medicare and Commercial products.

#### **CODING**

##### **BlueCHiP for Medicare and Commercial Products**

The following CPT code is covered when criteria are met:

**64566** Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming

#### **RELATED POLICIES**

Prior Authorization via Web-Based Tool for Procedures

#### **PUBLISHED**

Provider Update, July 2018

Provider Update, July 2017

Provider Update, June 2016

Provider Update, December 2015

Provider Update, January 2015

Provider Update, December 2013  
Provider Update, July 2012

## REFERENCES

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2. Burton C, Sajja A, Latthe PM. Effectiveness of percutaneous posterior tibial nerve stimulation for overactive bladder: a systematic review and meta-analysis. *Neurourol Urodyn* 2012; 31(8):1206-16.
3. Levin PJ, Wu JM, Kawasaki A et al. The efficacy of posterior tibial nerve stimulation for the treatment of overactive bladder in women: a systematic review. *Int Urogynecol J* 2012; 23(11):1591-7.
4. Moosdorff-Steinhauser HF, Berghmans B. Effects of percutaneous tibial nerve stimulation on adult patients with overactive bladder syndrome: A systematic review. *Neurourol Urodyn* 2013; 32(3):206-14.
5. Gaziev G, Topazio L, Iacovelli V et al. Percutaneous tibial nerve stimulation (PTNS) efficacy in the treatment of lower urinary tract dysfunctions: a systematic review. *BMC Urol* 2013; 13:61.
6. Shamliyan T, Wyman J, Kane RL. Nonsurgical Treatments for Urinary Incontinence in Adult Women: Diagnosis and Comparative Effectiveness. Agency for Healthcare Research and Quality; Rockville (MD), 2012. Available online at: <http://effectivehealthcare.ahrq.gov/ehc/products/169/834/urinary-incontinence-treatment-report-130909.pdf>.
7. Finazzi-Agro E, Petta F, Sciobica F et al. Percutaneous tibial nerve stimulation effects on detrusor overactivity incontinence are not due to a placebo effect: a randomized, double-blind, placebo controlled trial. *J Urol* 2010; 184(5):2001-6.
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9. MacDiarmid SA, Peters KM, Shobeiri SA et al. Long-term durability of percutaneous tibial nerve stimulation for the treatment of overactive bladder. *J Urol* 2010; 183(1):234-40.
10. Peters KM, Carrico DJ, Perez-Marrero P et al. Randomized trial of percutaneous tibial nerve stimulation versus sham efficacy in the treatment of overactive bladder syndrome: results from the SUMiT trial. *J Urol* 2010; 183(4):1438-43.

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