

## Medical Coverage Policy | Posterior Tibial Nerve Stimulation (PTNS) for Urinary Dysfunction



**EFFECTIVE DATE:** 12/01/2014  
**POLICY LAST UPDATED:** 11/04/2014

### OVERVIEW

This policy documents coverage guidelines for posterior tibial nerve stimulation (PTNS) affecting nerves and sensation as a treatment for urinary dysfunction. Posterior tibial nerve stimulation (PTNS) is a technique of electrical neuromodulation used for treating voiding dysfunction. The tibial nerve is stimulated using a fine-needle electrode inserted slightly above the ankle, and low-voltage electrical current is delivered.

### PRIOR AUTHORIZATION

#### BlueCHiP for Medicare

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

#### Commercial Products

Not Applicable

### POLICY STATEMENT

#### BlueCHiP for Medicare:

PTNS for voiding dysfunctions, including but not limited to urinary frequency, urgency, incontinence and non-obstructive retention is covered when the criteria are met. PTNS standard treatment regimen (30-minute weekly sessions for 12 weeks once per lifetime).

**Note:** Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates consideration of governmental regulations from CMS (Centers for Medicare and Medicaid Services), such as national coverage determinations or local coverage determinations. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. Medicare and BCBSRI policies may differ. However, BlueCHiP for Medicare members must be offered, at least, the same services as Medicare offers.

#### Commercial:

PTNS for voiding dysfunctions, including but not limited to urinary frequency, urgency, incontinence and non-obstructive retention **is not medically necessary** as there is insufficient, long-term, peer reviewed scientific literature, including randomized controlled clinical trials to demonstrate its efficacy and to support its use.

### MEDICAL CRITERIA

#### BlueCHiP for Medicare

PTNS will be covered for overactive bladder (OAB) symptoms for patients who are:

- Either, resistance or intolerant to standard anticholinergic/antispasmodics drug therapy (i.e., failed treatment with two anticholinergic drugs, each taken for at least 4 weeks duration, prior to the PTNS therapy initiation).

Contraindications to PTNS include any of the following:

- A cardiac pacemaker,
- An implantable defibrillator,

- whether the patient is prone to excessive bleeding, if the patient has nerve damage that could impact either percutaneous tibial nerve or pelvic floor function or whether the patient is pregnant or planning to become pregnant during the duration of PTNS treatment.

## BACKGROUND

Percutaneous tibial nerve stimulation (PTNS) therapy is a minimally invasive neuromodulation treatment designed to provide sacral nerve stimulation through percutaneous electrical stimulation of the posterior tibial nerve. Sacral neuromodulation involves stimulation of the sacral nerve plexus which regulates bladder and pelvic floor function. In July 2005, the Urgent® PC Neuromodulation System (Uroplasty, Inc.) received 510(k) marketing clearance for percutaneous tibial nerve stimulation to treat patients suffering from urinary urgency, urinary frequency, and urge incontinence. This device was cleared as a class II "nonimplanted, peripheral nerve stimulator for pelvic floor dysfunction" because it was considered to be substantially equivalent to the previously cleared percutaneous Stoller afferent nerve system (PerQ SANS System) in 2001 (K992069, UroSurge, Inc.).

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. Posterior tibial nerve stimulation (PTNS) is a technique of electrical neuromodulation proposed for the treatment of voiding dysfunction including urinary frequency, urgency, incontinence, and nonobstructive retention in patients who have failed behavioral and/or pharmacologic therapies. Stimulating the posterior tibial nerve with PTNS is purported to improve voiding function and control. While the posterior tibial nerve is located near the ankle, it is derived from the lumbarsacral nerves (L4-S3), which control the bladder detrusor and perineal floor.

The procedure for PTNS consists of the insertion of a needle above the medial malleolus near the posterior tibial nerve followed by the application of low voltage (10mA, 1–10 Hz frequency) electrical stimulation that produces sensory and motor responses (i.e., a tickling sensation and flexion of the big toe and/or fanning of all the toes). Noninvasive PTNS has also been delivered with surface electrodes. PTNS studies have reported 30-minute sessions given weekly for 4–12 weeks. The usual schedule is one 30-minute session once per week for twelve weeks. Consideration has been given to increasing the frequency of treatments to 3 times per week to speed achievement of desired outcomes.

For BCBSRI Commercial members, the evidence is insufficient to permit conclusions concerning the effect of this technology on health outcomes. Randomized trials with appropriate control groups are needed to determine the durability and short- and long-term effects of PTNS on voiding dysfunction. In addition, further randomized trials are needed to determine appropriate maintenance therapy.

## COVERAGE

Benefits vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for surgery services and "not medically necessary" services benefit.

## CODING

The following CPT code is covered with prior authorization when criteria are met for BlueCHiP for Medicare and not medically necessary for Commercial products:

64566

## RELATED POLICIES

Preauthorization via Web-Based Tool for Procedures

## PUBLISHED

Provider Update	Jan 2015
Provider Update	Dec 2013
Provider Update	Jul 2012
Provider Update	Jan 2012
Provider Update	Oct 2010
Provider Update	Sep 2009
Provider Update,	Jun 2008
Policy Update	Aug 2007

## REFERENCES

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