

**EFFECTIVE DATE:** 01|01|2016

**POLICY LAST UPDATED:** 05|02|2017

## 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

### BlueCHiP for Medicare

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

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

**Note:** Blue Cross & Blue Shield of Rhode Island (BCBSRI) must follow Centers for Medicare and Medicaid Services (CMS) guidelines, such as national coverage determinations or local coverage determinations for all BlueCHiP for Medicare policies. Therefore, BlueCHiP for Medicare policies may differ from Commercial products. In some instances, benefits for BlueCHiP for Medicare may be greater than what is allowed by the CMS.

### Commercial Products

Percutaneous tibial nerve stimulation is considered not medically necessary for all indications, including but not limited to Urinary dysfunction, including but not limited to overactive bladder syndrome, neurogenic

bladder, urinary frequency, urgency, incontinence, and retention as the evidence is insufficient to determine the effects of the technology on health outcomes.

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

Percutaneous tibial nerve stimulation 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 services not medically necessary.

### **BACKGROUND**

Altering the function of the posterior tibial nerve with percutaneous tibial nerve stimulation (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, anticholinergics), obesity, psychogenic factors, and disease (eg, multiple sclerosis, spinal cord injury, detrusor hyperreflexia, diabetes with peripheral nerve involvement). The current indication cleared by the U.S. Food and Drug Administration (FDA) for PTNS is overactive bladder (OAB), which is defined as the presence of urinary urgency, with or without urgency urinary incontinence, ie, 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 plantarflexion 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 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.

### **Regulatory Status**

In July 2005, the Urgent® PC Neuromodulation System (Uroplasty Inc.) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for percutaneous tibial nerve stimulation to treat patients suffering from urinary urgency, urinary frequency, and urge incontinence. In 2010, the cleared indication was changed to “overactive bladder (OAB) and associated symptoms of urinary urgency, urinary frequency, and urge incontinence.” The Urgent PC Neuromodulation System is 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.

The evidence for percutaneous tibial nerve stimulation (PTNS) in individuals who have non-neurogenic urinary dysfunction including overactive bladder (OAB) includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. A number of RCTs have been published, including 2 key industry-sponsored RCTs, the OrBIT and SUMiT trials. Systematic reviews of the published trials have found short-term improvements with PTNS and have not identified long-term comparative studies. The largest, highest

quality study was the double-blinded, sham-controlled SUMiT trial. It reported a statistically significant benefit of PTNS and sham at 12 weeks. Two other sham-controlled RCTs, including 1 published in 2015, had mixed findings on short-term efficacy of PTNS. The nonblinded OrBIT trial found that PTNS was noninferior to medication treatment at 12 weeks. Longer term comparative data are not available after the initial 12-week treatment period. Up to 36 months of uncontrolled data are available but only for patients enrolled in RCTs who responded to an initial course of treatment who may not be representative of the patient population as a whole. For Commercial, the evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for PTNS in individuals who have neurogenic bladder includes several RCTs and a systematic review of RCTs and observational data. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Only a few RCTs evaluating tibial nerve stimulation for treating neurogenic bladder have been published to date and all but 1 performed transcutaneous stimulation rather than PTNS. Studies varied widely in factors, such as the study population and comparison intervention. Study findings have not reported that tibial nerve stimulation significantly improved incontinence symptoms and other outcomes. For Commercial, the evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for PTNS in individuals who have fecal incontinence includes several RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The available RCTs have not found a clear benefit of PTNS. Neither of the sham-controlled trials found that active stimulation was superior to sham for achieving the primary outcome, at least a 50% reduction in mean weekly fecal incontinence episodes. The larger shamcontrolled RCT did find a significantly greater decrease in absolute number of weekly incontinence episodes in the active treatment group, but the overall trial findings did not suggest superiority of PTNS over sham treatment. Systematic reviews have not conducted pooled analyses. For Commercial, the evidence is insufficient to determine the effects of the technology on health outcomes.

For BlueCHiP for Medicare, the CMS will allow coverage for Posterior Tibial Nerve Stimulation for Voiding Dysfunction for beneficiaries with overactive bladder syndrome (OBS) as a less invasive “third-line treatment” for selected patients who meet the medical criteria outlined above.

## **CODING**

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

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

## **RELATED POLICIES**

Preauthorization via Web-Based Tool for Procedures

## **PUBLISHED**

Provider Update, July 2017  
Provider Update, June 2016  
Provider Update, December 2015  
Provider Update, January 2015  
Provider Update, December 2013  
Provider Update, July 2012  
Provider Update, January 2012  
Provider Update, October 2010  
Provider Update, September 2009

## REFERENCES

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14. Knowles CH, Horrocks EJ, Bremner SA, et al. Percutaneous tibial nerve stimulation versus sham electrical stimulation for the treatment of faecal incontinence in adults (CONFIDeNT): a double-blind,

multicentre, pragmatic, parallel-group, randomised controlled trial. Lancet. Oct 24 2015;386(10004):1640-1648. PMID 26293315

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