Medical Coverage Policy | Percutaneous Tibial Nerve Stimulation

EFFECTIVE DATE: 01|01|2016

POLICY LAST UPDATED: 10|20|2015

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:** Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates consideration of governmental regulations from the Centers for Medicare and Medicaid Services (CMS), 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 that Medicare offers.

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 there is insufficient peer-reviewed literature to demonstrate that the procedure is effective.

BlueCHiP for Medicare and Commercial Products
Percutaneous tibial nerve stimulaton 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 Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for limitations of benefits/coverage when services are not medically necessary.

BACKGROUND

Percutaneous tibial nerve stimulation 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 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.

PTNS is not cleared by the 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 overactive bladder (OAB); an initial course of 12 weekly sessions of tibial nerve stimulation followed by a personalized schedule of follow-up treatments.

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. There is also insufficient evidence that PTNS is effective for other conditions such as fecal incontinence.

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, 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
Provider Update, June 2008

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