Medical Coverage Policy | Percutaneous Tibial Nerve Stimulation

EFFECTIVE DATE: 09|01|2018
POLICY LAST UPDATED: 09|15|2021

OVERVIEW

Percutaneous tibial nerve stimulation (PTNS); also known as posterior tibial nerve stimulation) is an electrical neuromodulation technique 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 Medicare Advantage Plans and recommended for Commercial products and obtained via the online tool for participating providers. See the Related Policies section.

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products
PTNS for overactive bladder syndrome is covered when the medical criteria are met.

Medicare Advantage Plans 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 applicable coverage for surgery.

BACKGROUND

Common causes of non-neurogenic voiding dysfunction are pelvic floor neuromuscular changes (eg, from pregnancy, childbirth, surgery), inflammation, medication (eg, diuretics, anticholinergics), obesity, and psychogenic factors. Overactive bladder is a non-neurogenic voiding dysfunction characterized by urinary frequency, urgency, urge incontinence, and nonobstructive retention.

Neurogenic bladder dysfunction is caused by neurologic damage in patients with multiple sclerosis, spinal cord injury, detrusor hyperreflexia, or diabetes with peripheral nerve involvement. The symptoms include overflow incontinence, frequency, urgency, urge incontinence, and retention.

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.

Altering the function of the posterior tibial nerve with 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.

Administration of PTNS consists of inserting 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 plantarflexion 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 to treat 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.

Regulatory Status
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. Additional PTNS devices have been cleared for marketing through the 510(k) process.

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 Medicare Advantage Plans and Commercial products.

Wireless technology is evolving for the treatment of overactive bladder; it is approved in Europe. BlueWind (BlueWind Medical) is a wireless, battery-less, miniature implantable neurostimulator activated by an external device worn at the ankle.

CODING

Medicare Advantage Plans 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, November 2021

Provider Update, October 2020
Provider Update, November 2019
Provider Update, July 2018
Provider Update, July 2017

REFERENCES

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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.
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