Percutaneous Tibial Nerve Stimulation

(701106)
(Formerly Posterior Tibial Nerve Stimulation for Voiding Dysfunction)

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<tr>
<th>Medical Benefit</th>
<th>Effective Date: 10/01/15</th>
<th>Next Review Date: 07/16</th>
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<tr>
<td>Preauthorization</td>
<td>No</td>
<td>Review Dates: 09/09, 09/10, 09/11, 07/12, 07/13, 07/14, 07/15</td>
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The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Preauthorization is not required but is recommended if, despite this Protocol position, the physician feels this service is medically necessary. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

Description

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

Background

Altering the function of the posterior tibial nerve with 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 (e.g., from pregnancy, childbirth, surgery), inflammation, medication (e.g., diuretics, anticholinergics), obesity, psychogenic factors, and disease (e.g., multiple sclerosis, spinal cord injury, detrusor hyperreflexia, diabetes with peripheral nerve involvement). The current FDA-cleared indication for PTNS is overactive bladder (OAB), which is defined as the presence of urinary urgency, with or without urgency urinary incontinence, that is 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 (i.e., 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 (see the Sacral Nerve Neuromodulation/Stimulation Protocol), 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.) received 510(k) marketing clearance from FDA 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 urgency, urgency, frequency, and urge incontinence.” The Urgent PC Neuromodulation System is not FDA-cleared for other indications, such as the treatment of fecal incontinence.

Related Protocols

Biofeedback as a Treatment of Fecal Incontinence or Constipation
Biofeedback as a Treatment of Urinary Incontinence in Adults
Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence
Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence
Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy
Sacral Nerve Neuromodulation/Stimulation
Transanal Radiofrequency Treatment of Fecal Incontinence

Policy

Percutaneous tibial nerve stimulation is considered investigational for all indications, including but not limited to the following:

- Urinary dysfunction, including but not limited to overactive bladder syndrome, neurogenic bladder, urinary frequency, urgency, incontinence, and retention
- Fecal incontinence.

Medicare Advantage

Percutaneous tibial nerve stimulation (PTNS) is considered medically 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 greater than 50% decrease in OBS symptoms with the initial treatment and then relapse.
Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References
We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


22. Local Coverage Determination (LCD): Posterior Tibial NERVE STIMULATION for VOIDing Dysfunction (L31391), Revision Effective Date for services performed on or after 09/01/2014.