

Protocol

Posterior Tibial Nerve Stimulation for Voiding Dysfunction

(701106)

Medical Benefit	Effective Date: 10/01/13	Next Review Date: 07/15
Preauthorization	No	Review Dates: 09/09, 09/10, 07/11, 07/12, 07/13, 07/14

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products 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, you feel 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

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. The recommended course of treatment is 12 weekly 30-minute sessions followed by an individualized maintenance schedule.

Background

Altering the function of the posterior tibial nerve with PTNS is believed to improve voiding function and control. While 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 and anticholinergics), obesity, psychogenic factors, and disease (e.g., multiple sclerosis, spinal cord injury, detrusor hyper-reflexia, diabetes with peripheral nerve involvement).

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 plantar flexion 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.

Regulatory Status

In July 2005, the Urgent® PC Neuromodulation System (Uroplasty Inc.) received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) for percutaneous tibial nerve stimulation to treat patients suffering from urinary urgency, urinary frequency, and urge incontinence. The 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.).

Related Protocols

Pelvic Floor Stimulation as a Treatment of Urinary Incontinence

Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)

Sacral Nerve Neuromodulation/Stimulation

Policy (Formerly Corporate Medical Guideline)

Posterior tibial nerve stimulation is considered **investigational** for urinary dysfunction, including but not limited to overactive bladder syndrome, neurogenic bladder, urinary frequency, urgency, incontinence and retention.

Medicare Advantage

Posterior tibial nerve stimulation is considered **not medically necessary** for all indications dealing with voiding dysfunction, including but not limited to, treatment of overactive bladder symptoms such as urinary urgency, urinary frequency and urge incontinence, stress incontinence, non-obstructive urinary retention and interstitial cystitis.

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.

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