

POSTERIOR TIBIAL NERVE STIMULATION

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Overview

Posterior (or percutaneous) tibial nerve stimulation (PTNS), also referred to as posterior tibial (or percutaneous) neuromodulation, is a minimally invasive, office-based treatment for patients with overactive bladder (OAB), that is refractory to behavioral and pharmacologic therapies. OAB is associated with complaints (symptoms) of urinary urgency, with or without urge urinary incontinence, usually with increased daytime frequency and nocturia.

Normal urinary control is dependent upon competent neural pathways and coordination among the central and peripheral nervous systems. Disrupted nerve signals can lead to OAB. Neuromodulation incorporates electrical stimulation that targets specific neural tissue. To modulate urinary dysfunction, the signals must be delivered to the nerve tissue affecting bladder activity. The tibial nerve is a mixed nerve containing L4-S3 fibers (the same spinal segments that provide innervation to the bladder and pelvic floor).

The device used to deliver PTNS is a combination of a small gauge needle electrode, a surface grounding electrode, lead wires, and a low-voltage generator. The needle electrode is inserted percutaneously into the tibial nerve approximately two inches cephalad to the medial malleolus. After the lead wire and surface electrode are attached, the device is turned on and amplitude is slowly increased. Treatment is continued for approximately 30 minutes.

Definitions

Urge Urinary Incontinence - the complaint of involuntary leakage (of urine) accompanied by or immediately preceded by urgency.

Stress Urinary Incontinence - the complaint of involuntary leakage (of urine) on effort or exertion, or on sneezing or coughing.

Nocturia - the complaint that the individual has to wake at night one or more times to urinate.

Increased Daytime Frequency - the complaint by the individual who considers that he/she voids too often during the day.

Urgency - the complaint of a sudden compelling desire to pass urine, which is difficult to defer.

Urinary incontinence – the complaint of any involuntary leakage of urine.

Covered Services

PTNS requires preauthorization.

A once weekly, 12-week trial of PTNS will be authorized when all of the following criteria are met:

1. The plan member has one or more of the following complaints (symptoms):
 - a. Urge urinary incontinence
 - b. Increased daytime frequency and/or nocturia
 - c. Urinary urgencyand been diagnosed with OAB (in the absence of infection or other etiology, such as, incontinence secondary to impaired mobility or cognition, or incontinence secondary to a neurologic condition (such as diabetic peripheral neuropathy, or MS).
2. The plan member has not responded satisfactorily to behavioral treatments.¹
3. The plan member has not responded satisfactorily to or cannot tolerate pharmacologic treatments.²

Tapering and maintenance treatment is necessary to successfully treat OAB with PTNS. A tapering protocol is customized to the individual patient. During tapering, the interval between treatment visits is lengthened stepwise by intervals of 1 week until regression of efficacy is noted. Most patients are maintained with 12 to 18 PTNS treatments per year. A typical PTNS treatment regimen is as follows:

- First year: PTNS trial of 12 treatments, one treatment per week for twelve weeks. If successful, the trial is followed by tapering and maintenance over the next 9 months (up to 18 treatments will be authorized for tapering and maintenance).
- Second and subsequent years: 12-18 treatments per 12 months.

Tapering and maintenance treatment will be authorized when there has been successful completion of a 12-week PTNS trial evidenced by a significant reduction in symptoms documented in the plan member's medical record.

Exclusions

1. PTNS for stress urinary incontinence (SUI).

¹ Behavioral therapy is recommended as the first-line treatment option for OAB. Behavioral therapy includes fluid management, prompted voiding, bladder training, and pelvic floor exercises. The success of behavioral therapy is highly dependent on the motivation and dedication of the patient.

² The mainstay of pharmacologic therapy for OAB is anticholinergics, a class of drugs that decreases the incidence of involuntary muscle contractions and improves the capacity of the bladder to store urine. The effectiveness of anticholinergic agents, such as oxybutynin, for the treatment of OAB have been well documented. Published studies have shown that most anticholinergic drugs are equally effective, with decreases in incontinence episodes ranging from 50% to 80%. Although similar in efficacy, anticholinergics have varying drug-drug interaction and side-effect profiles which affect the drug selection process for a particular patient. Frequently, pharmacologic treatment of OAB is discontinued due to intolerable side effects or lack of efficacy or a combination of both.

References

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3. Rosenberg MT, Dmochowski RR. Overactive Bladder: Evaluation and Management in Primary Care. *Cleveland Clinic Journal of Medicine* 2005 Feb;72(2):149-56.
4. Van Balken MR, Vandoninck V, Gisolf K, Vergunst H, Kiemeneij L, Debruyne F, Bemelmans B. Posterior Tibial Nerve Stimulation as Neuromodulative Treatment of Lower Urinary Tract Dysfunction. *J Urol* 2001 Sep;166:914-18.
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6. Percutaneous Afferent Neuromodulation for the Refractory Overactive Bladder: Results of a Multicenter Study. *J Urol* 2001 Apr;165:1193-98.
7. Van der Pal F, Van Balken MR, Heesakkers J, Debruyne F, Bemelmans B. Percutaneous Tibial Nerve Stimulation in the Treatment of Refractory Overactive Bladder Syndrome: Is Maintenance Treatment Necessary? *BJU International* 2006;97:547-50.
8. Vandoninck V, Van Balken M, Finazzi Agro E, Petta F, Micali F, Heesakkers J, Debruyne F, Kiemeneij L, Bemelmans B. Percutaneous Tibial Nerve Stimulation in the Treatment of Overactive Bladder: Urodynamic Data. *Neurourol Urodyn* 2003;22:227-32.

Codes

The correct CPT code to use for PTNS is the unlisted CPT code 64999. CPT codes for percutaneous implantation of neurostimulator electrodes (i.e., 64553-64565) are not appropriate since PTNS uses percutaneously inserted electrodes rather than percutaneously implanted electrodes. The stimulation devices used in PTNS are not implanted so CPT code 64590 is also not appropriate.

Codes	Number	Description
CPT	64999	Unlisted procedure, nervous system

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Committee Review Dates:

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IMPORTANT NOTE

Not all services are covered for all commercial products or employer groups. Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this Medical Policy & Criteria Statement.