



## POSTERIOR TIBIAL NERVE STIMULATION

**Number:** 200711-0001

**Effective Date:** 11/27/2007

**Revision Date:** 06/28/2011

### 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). OAB is a chronic condition 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 (Urgent® PC Neuromodulation System, Uroplasty, Inc.) 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. The stimulator is left in place with the patient controlling the power for 30 minutes. Treatments are usually given once weekly for 12 consecutive weeks, but treatment variations include an accelerated protocol (3 times per week for 4 weeks). Following the initial treatment phase, maintenance treatment is continued indefinitely. The protocol for maintenance treatment is tailored to each individual patient; typically one treatment is required every 2 to 3 weeks.

Because OAB is a chronic condition it is important to evaluate PTNS over the long term. Efficacy of PTNS during the initial treatment phase does not automatically imply efficacy or improved outcomes during the maintenance phase. Therefore when evaluating PTNS as a treatment for OAB, it must be shown that PTNS is effective in reducing symptoms during the 12-week treatment phase and that response is durable.

Three randomized controlled studies report short-term efficacy of PTNS. The magnitude of benefit is less certain. Peters et al. (2010) conducted a high-quality multicenter randomized, controlled double-blinded trial (the SUMiT trial) comparing PTNS to a sham control (TENS). A total of 220 patients were randomized. Both groups



received 12 weekly 30 minute sessions. The proportion of responders based on the primary outcome (patient reporting moderate or marked improvement in symptoms at the end of the trial) was 60 of 110 (54.5%) in the PTNS group and 25 of 110 in the sham group. This is statistically significant. However, the definition of “responders” used was a patient rating of either improved or cured at the end of the trial (single-item global assessment), which is the most subjective of the outcome measures). Defining responders this way is not a standard approach in incontinence research. Finazzi-Agro et al. (2010) also conducted a randomized sham controlled study of PTNS. This small trial of 35 women had some methodologic limitations (not double-blinded, intent-to-treat analysis not performed, outcomes were not ascertained in an independent manner). The primary outcome measure was a patient-reported greater than 50% reduction in incontinent episodes. This trial treated patients 3 times a week for 4 weeks rather than one time per week for 12 weeks. This trial reported a large difference in response rates for frequency of incontinent episodes (71% vs. 0%). The third randomized, controlled trial (OrBIT trial) was a comparison of PTNS to extended release tolterodine. (Peters et al. 2009) The primary outcome of this noninferiority trial was mean reduction in number of voids per day. There was no statistically significant difference between the PTNS and tolterodine groups. This trial did not meet several quality indicators including lack of double-blinding, unequal intensity of treatment with no placebo control, and lack of intent-to-treat analysis. Furthermore, the results of this noninferiority trial were not reported correctly.

There is one study that evaluated the durability of treatment response beyond the initial treatment period. This was a 1 year follow-up of the 33 responders in the OrBIT trial (Peters et al., 2009) These 33 responders received a mean of 12.1 treatments between the 12-week and 12 month visits. There was a median of 17 days between treatments. At 12 months follow-up, 24 patients were self-reported responders. The primary outcome was the mean reduction in number of voids per 24 hours. The lack of evidence of durability raises the question of whether short-term efficacy can be maintained over the long term. PTNS has little practical utility unless the treatment effect can be maintained over long periods. This will require demonstration in high-quality trials that show that the maintenance phase of the treatment is effective.

### **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.



## Policy

Due to the nature of this treatment, it is important to show both short-term efficacy and long-term durability in order to conclude that PTNS improves health outcomes for plan members with chronic OAB. Based on our technology assessment, FCHP has determined that the scientific evidence is not sufficient to permit conclusions on (1) the long-term durability of PTNS on the treatment of OAB, (2) the effect of PTNS on health outcomes for plan members with chronic OAB, or (3) whether PTNS is as beneficial as alternative treatments for chronic OAB. Therefore, PTNS is considered not medically necessary for the treatment of OAB for commercial plan members.<sup>1</sup>

Effective May 22, 2011, in accordance with contractual obligation, FCHP will cover PTNS for Medicare Advantage plan members (Fallon Senior Plan and NaviCare) and MassHealth plan members consistent with medical necessity guidelines specified in the NHIC LCD for Percutaneous Tibial Nerve Stimulation. This LCD is available for reference at: [http://www.medicarenhic.com/ne\\_prov/policies.shtml](http://www.medicarenhic.com/ne_prov/policies.shtml).

### **PTNS for Medicare Advantage and MassHealth plan members requires prior authorization from FCHP.**

For Medicare Advantage (Fallon Senior Plan and NaviCare) and MassHealth plan members only:

1. FCHP will authorize one (per lifetime) 12-week treatment regimen (consisting of 30 minute sessions given once weekly for 12 consecutive weeks) for the treatment of symptoms of OAB that is either refractory or intolerant to standard anticholinergic drug therapy (i.e., failed treatment with at least two anticholinergic drugs each taken for at least 4 weeks duration prior to the initiation of PTNS).
2. FCHP will authorize continuation of PTNS for plan members who complete and show response to the 12-week treatment regimen. Response is defined as at least a 50% improvement in voiding symptoms (based on documentation such as patient voiding diaries). The treatment regimen for continued PTNS is tailored to each individual plan member; typically one treatment is administered every 2 to 3 weeks (26 treatments per 12 month maximum).

Note: Per NHIC LCD and consistent with manufacturer instructions, this treatment should generally be delivered in an office setting (place of service = 11).

---

<sup>1</sup> Although FCHP's Technology Assessment Committee has determined that PTNS does not meet FCHP's Technology Assessment Criteria and is therefore not medically necessary, the Federal Employees Health Benefits Program (FEHBP) requires coverage for all FDA-approved drugs, devices or biological products. Therefore, PTNS is covered for FEHBP members if an FCHP Medical Director determines that it is medically necessary. (FEHBP Carrier Letter No. 2001-27).

## References

1. Sand PK, Dmochowski RR. Analysis of the Standardisation of Terminology of Lower Urinary Tract Dysfunctions: Report from the Standardisation Subcommittee of the International Continence Society. *Neurourol Urodynam* 2002 Mar;21(2):167-78.
2. Goode PS. Behavioral and Drug Therapy for Urinary Incontinence. *Urology* 2004 Mar;63(Suppl 3A):58-64.
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, Kiemeney L, Debruyne F, Bemelmans B. Posterior Tibial Nerve Stimulation as Neuromodulative Treatment of Lower Urinary Tract Dysfunction. *J Urol* 2001 Sep;166:914-18.
5. Amarenco G, Sheikh Ismael S, Even Schneider A, Paibaut P, Demaille-Wlodyka S, Parratte B, Kerdraon J. Urodynamic Effect of Acute Transcutaneous Posterior Tibial Nerve Stimulation in Overactive Bladder. *J Urol* 2003 Jun;169:2210-15.
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, Kiemeney L, Bemelmans B. Percutaneous Tibial Nerve Stimulation in the Treatment of Overactive Bladder: Urodynamic Data. *Neurourol Urodyn* 2003;22:227-32.
9. van Balken MR, Vergunst H, Bemelmans BL. Prognostic Factors for Successful Percutaneous Tibial Nerve Stimulation. *Eur Urol*. 2006 Feb;49(2):360-5.
10. Hayes Directory. Electrical Percutaneous Tibial Nerve Stimulation for Urinary Voiding Dysfunction. September 18, 2008. © 2008 Winifred S. Hayes, Inc.
11. BlueCross BlueShield Association Technology Evaluation Center. Percutaneous Tibial Nerve Stimulation for the Treatment of Voiding Dysfunction. March 2011. © Blue Cross and Blue Shield Association.
12. Peters KM, Carrico DJ, Perez-Marrero RA, et al. Randomized Trial of Percutaneous Tibial Nerve Stimulation Versus Sham Efficacy in the Treatment of Overactive Bladder Syndrome: Results from the SUmIT Trial. *J Urol*. 2010;183:1438-43.
13. Peters KM, MacDiarmid SA, Wooldridge LS, et al. Randomized Trial of Percutaneous Tibial Nerve Stimulation Versus Extended-Release Tolterodine: Results for the Overactive Bladder Innovative Therapy Trial. *J Urol*. 2009;182:1055-61.
14. MacDiarmid SA, Peters KM, Shobeiri A, et al. Long-Term Durability of Percutaneous Tibial Nerve Stimulation for the Treatment of Overactive Bladder. *J Urol*. 2010;183:234-40.



15. Finazzi-Agro E, Petta F, Sciobica F, et al. Percutaneous Tibial Nerve Stimulation Effects on Detrusor Overactivity Incontinence Are Not Due to a Placebo Effect: A Randomized, Double-Blind, Placebo Controlled Trial. *J Urol.* 2010;184:2001-6.
16. National Heritage Insurance Company (NHIC) Local Coverage Determination (LCD) for Percutaneous Tibial Nerve Stimulation. Original Effective Date: 05/22/2011.

### Coding

Effective for services performed on or after January 1, 2011, the correct CPT code to use for PTNS is 64566. For services performed prior to January 1, 2011, 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.

Physicians should use the diagnosis code(s) that most accurately describe the patient's condition. The following list includes diagnosis codes that may be applicable:

- 788.31 Urge incontinence
- 788.33 Mixed incontinence – urge and stress
- 788.34 Incontinence without sensory awareness
- 788.41 Urinary frequency
- 788.63 Urgency of urination

Codes	Number	Description
CPT	64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming

Copyright © 2011 American Medical Association, Chicago, IL

### Products to Which This Policy Applies

- ⊕ FCHP Direct & Select Care
- ⊕ Fallon Preferred Care (PPO)
- ⊕ Major Medical
- ⊕ MassHealth
- ⊕ Companion Care
- ⊕ Commonwealth Care
- ⊕ NaviCare
- ⊕ Fallon Senior Plan™
- ⊖ Summit Elder Care® PACE (Note: With the exception of emergency care, all services for Summit ElderCare® PACE participants must be authorized and arranged by the Summit ElderCare (SE) Interdisciplinary Team (IDT) overseeing the care for that participant. The applicable IDT can be determined by the HCO code on the participant ID card. The site codes and corresponding telephone numbers are: SW1-SE East Mtn St. Worcester-508-852-2026, SW2-SE Grafton St.



Worcester-508-373-7400, SC1-SE Charlton-508-434-3200, SL1-SE Leominster-978-401-3100.)

### **Committee Review Dates**

Technology Assessment Subcommittee: 10/23/07, 11/27/07, 05/07/09, 09/22/09, 10/27/09, 12/28/10

Technology Assessment Committee: 04/08/08, 12/16/09, 01/25/11, 06/28/2011

#### **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.