

**Effective Date: November 2009;**  
**Revised [11/11; 11/13]**

**Subject: Tibial Nerve Stimulation for Urinary Symptoms and Incontinence**

**Overview:** Electrical percutaneous tibial nerve stimulation (PTNS) is a peripheral technique that achieves its effect by periodic percutaneous stimulation of the posterior tibial nerve. PTNS is administered to improve urological symptoms including, but not limited to, urinary frequency, urgency, and urge incontinence.

**Policy and Coverage Criteria:**

Tibial nerve stimulation is **NOT** covered for the treatment of urinary symptoms and incontinence. It is considered not medically necessary.

**Exclusions:** N/A

**Supporting Information:**

1. Technology Assessment: Electrical stimulation of the tibial nerve has been proposed as a treatment option for urinary incontinence. The posterior tibial nerve is a mixed sensory and motor nerve containing fibers originating from the lumbar and sacral areas of the spine. The sacral nerves modulate the somatic and autonomic nerve supply to the bladder and urinary sphincter.

A fine needle is inserted into the skin just cephalad to the medial malleolus (at the SP6 acupuncture point) to access the posterior tibial nerve. A small surface electrode is then placed over the medial aspect of the calcaneus on the same leg. The lead wire is first connected to the stimulator, and then the needle electrode clip is connected to the needle electrode. The stimulator produces an adjustable electrical pulse that travels to the sacral nerve plexus via the tibial nerve. Stimulation is titrated from 0 to 10 mA, with fixed pulse 200 microseconds ( $\mu$ s) at frequency 20 hertz (Hz). Proper needle placement is confirmed with flexion of the great toe and/or ipsilateral digits 2 through 5. Patients may also notice stretching outward of their toes. PTNS stimulation should not cause pain. The stimulator is left with the patient controlling the power setting for 30 minutes. Treatments are given for 10 to 12 consecutive weeks. Maintenance treatment is usually needed and tailored to each specific patient.

2. Literature Review: There is an increasing body of literature evaluating the use of PTNS for the treatment of urinary symptoms and incontinence. Some published RCTs have shown positive short-term results. However, further studies establishing long-term results and efficacy are needed.

Peters et al. (2013) published 3-year results of 29 patients. The patients had undergone the initial 12-week PTNS study and then were prescribed a fixed schedule 14-week tapering protocol followed by a personal PTNS treatment plan for overactive bladder symptoms. Patients received a median of 1.1 treatments per month over the 36 months. Results found improvements in median voids per day, nighttime voids, and urge incontinence episodes as compared to baseline.

A review by Schreiner et al. (2013) assessed the literature around electrical stimulation for urinary incontinence in women. The reviewers noted PTNS showed promising results with a short follow-up period, but further randomized trials are needed to determine the magnitude of benefits.

A comparison of cost and cost-effectiveness of PTNS and sacral nerve stimulation for treatment of overactive bladder was detailed by Martinson et al. (2013). The authors used a Markov model and cost data from average Medicare national physician payments. Clinical effectiveness and patient adherence rates were estimated from clinical literature. Results found Both treatments to be safe, but PTNS has substantially lower cost.

Burton, et al. (2013) performed a systematic review and meta-analysis on the effectiveness of PTNS for overactive bladder. Results found significant improvement in OAB symptoms using PTNS, which is comparable to the effect of antimuscarinics but with a better side effect profile. However, the reviewers noted the data only described short-term outcomes. Further long-term data and health economic analysis are needed before PTNS can be recommended as a practical treatment option.

Ridout and Yoong (2010) published a literature review evaluating evidence of percutaneous tibial nerve stimulation for overactive bladder syndrome. The authors found the mode of action of PTNS is still uncertain, but it may have a role as a useful, minimally invasive treatment option in medically refractory OABS with a 60-81% response rate. Ridout and Yoong also concluded there is insufficient data to advocate PTNS as a first-line treatment due to its cost and long-term treatment regimen.

Peters et al. (2010) published results of an RCT comparing PTNS with sham treatment in patients with OABS. 220 adults with OABS were randomized 1:1 to 12 weeks of treatment with weekly PTNS or sham therapy. Overactive bladder and QOL questionnaires, as well as 3-day voiding diaries were completed at baseline and at 13 weeks. Subject global response assessments were completed at week 13. Results showed PTNS subjects had statistically significant improvement in bladder symptoms with 54.5% reporting moderately or markedly improved responses compared to 20.9% of sham subjects from baseline ( $p < .001$ ). Voiding diary measures after 12 weeks found PTNS subjects had significant improvements in frequency, nighttime voids, voids with moderate to severe urgency and urinary urge incontinence episodes compared to sham. Based on the results, researchers concluded PTNS is safe and effective in treating overactive bladder symptoms.

Results of a small RCT comparing PTNS to placebo in women with detrusor overactivity incontinence was published by Finazzi-Agro et al. (2010). 35 patients who did not respond to antimuscarinic therapy were randomized to either PTNS or control. PTNS patients ( $n=18$ ) were treated with 12 sessions. The control group ( $n=17$ ) received a placebo treatment using a 34 gauge needle placed in the medial part of the gastrocnemius muscle. Sessions last for 30 minutes, 3 times weekly. All patients were evaluated with bladder diaries and QOL scores before and after treatment. Patients showing a reduction in urge incontinence episodes greater than 50% were considered responders. 17 PTNS patients and 15 control patients completed the study. 71% of patients in the PTNS group were considered responders. Improvement in the number of incontinence episodes, number of voids, voided volume and incontinence quality of life score were statistically significant in the PTNS group, but not in the placebo. Finazzi-Agro et al. found PTNS to be an effective treatment for patients with detrusor overactivity incontinence.

MacDiarmid et al. (2010) described the results of the second phase of a study of PTNS for OABS. The initial study period was 12 weeks. 32 subjects completed 6 additional months of PTNS therapy and 25 completed the full 12 months. Outcome measures included voiding diary data, overactive bladder questionnaires, global response assessments and safety assessments. Patients received an average of 12.1 treatments during an average of 263 days, with a mean of 21 days between treatments. Global response assessments showed sustained improvement from 12 weeks at 6 and 12 months, with 94% and 96% of responders, respectively. The authors found the statistically significant improvements at 12 weeks demonstrated excellent durability through 12 months.

A 2009 case series by Kabay et al. reported on the effects of peripheral tibial nerve stimulation on urodynamic findings in 32 patients with Parkinson's disease. The study group had storage issues, overactive bladder, and involuntary detrusor contraction. While results showed significant improvement in symptoms, the authors cautioned that the data should be verified in a prospective multicenter study before being introduced into routine practice.

A prospective observational study (Nuhoglu et al., 2006) investigated the efficacy of a tibial nerve stimulation device in 35 patients with overactive bladder unresponsive to pharmacotherapy. Patients were treated once a week for 30 minutes for a total of 10 weeks. Three-day voiding diaries, quality of life questionnaires, and cystometry were completed before and after treatment and at one year following the treatment. The initial success rate was 54%, with improvements seen in voiding diary parameters, urodynamic parameters and quality of life scores. At one year, efficacy of success was maintained in 23% of the 32 patients. These results led the researchers to conclude the nerve stimulation had positive short-term effects, but that efficacy decreases after

about 3 months. They also proposed the treatment may need to be repeated at regular intervals to prevent relapse, but further studies would need to be conducted to confirm this hypothesis.

A 2005 study by Karademir et al. compared outcomes between patients treated with the percutaneous Stoller Afferent Nerve Stimulator (SANS) alone and patients that received both SANS plus a low-dose of anticholinergic medication (n=22). All patients underwent 60 minutes of SANS treatment once a week for a total of eight weeks. The treatment response rate was 61.6% in the SANS group and 83.2% in the SANS plus medication group. The researchers noted the best symptomatic improvements were seen in patients with urge incontinence.

Finazzi et al. (2005) found little difference in outcomes in 35 patients randomly assigned to PTNS weekly (group 1) versus 3 times per week (group 2). Thirty-six percent of group 1 incontinent patients and 45% of group 2 incontinent patients were completely cured after treatment.

Vondoninck et al. (2003a) evaluated 90 patients with overactive bladder (OAB) and found that PTNS delayed onset of detrusor instability (DI) but could not abolish it. Additional studies conducted by Vondoninck et al. assessed patients (n=35 to 39) treated with PTNS and concluded that PTNS is an effective, minimally invasive procedure to treat urge incontinence and idiopathic voiding dysfunction (Vondoninck et al., 2003b, 2003c, 2004).

### 3. Benchmarks:

BCBSMA: Posterior tibial nerve stimulation (PTNS) for urinary dysfunction, including but not limited to overactive bladder syndrome, neurogenic bladder, urinary frequency, urgency, incontinence, and retention, is investigational.

[http://www.bluecrossma.com/common/en\\_US/medical\\_policies/583%20Posterior%20Tibial%20Nerve%20Stimulation%20for%20Voiding%20Dysfunction%20prn.pdf#page=2](http://www.bluecrossma.com/common/en_US/medical_policies/583%20Posterior%20Tibial%20Nerve%20Stimulation%20for%20Voiding%20Dysfunction%20prn.pdf#page=2)

Tufts Health Plan: Not covered

[http://www.tuftshealthplan.com/providers/pdf/mng/statements\\_of\\_non\\_coverage.pdf](http://www.tuftshealthplan.com/providers/pdf/mng/statements_of_non_coverage.pdf)

Anthem BCBS NH: PTNS is considered investigational and not medically necessary for all indications, including but not limited to:

- All indications dealing with urinary 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;
- All indications dealing with fecal dysfunction, such as incontinence, constipation, IBD, anal sphincter dysfunction.

[http://www.anthem.com/medicalpolicies/policies/mp\\_pw\\_c140988.htm](http://www.anthem.com/medicalpolicies/policies/mp_pw_c140988.htm)

CIGNA: Not covered

[http://www.cigna.com/customer\\_care/healthcare\\_professional/coverage\\_positions/medical/mm\\_0160\\_coverage\\_positioncriteria\\_electrical\\_stimulators.pdf](http://www.cigna.com/customer_care/healthcare_professional/coverage_positions/medical/mm_0160_coverage_positioncriteria_electrical_stimulators.pdf)

United Healthcare: Percutaneous tibial nerve stimulation is proven for the treatment of overactive bladder syndrome including urinary frequency, urgency, and urge incontinence.

[https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Policies%20and%20Protocols/Medical%20Policies/Medical%20Policies/Radiofreq\\_Therap\\_Tib\\_Nerv\\_Stim\\_Urin\\_Incont.pdf](https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Policies%20and%20Protocols/Medical%20Policies/Medical%20Policies/Radiofreq_Therap_Tib_Nerv_Stim_Urin_Incont.pdf)

### 4. Professional/Governmental Agencies:

CMS: There is no NCD for this procedure

FDA: 501k clearance for three devices

- K061333: Urgent PC Neuromodulation System [second generation device]
- K052025: Urgent PC Neuromodulation System [first generation device]
- K992069: UroSurge Percutaneous SANS TR

### Codes:

CPT:

64566 – Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming

## References:

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