MEDICAL POLICY

Excellus

SUBJECT: PERCUTANEOUS POSTERIOR TIBIAL NERVE STIMULATION (PPTNS)	EFFECTIVE DATE: 03/17/11 REVISED DATE: 03/15/12, 03/21/13, 03/20/14
POLICY NUMBER: 8.01.22 CATEGORY: Technology Assessment	PAGE: 1 OF: 6

- ***If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.***
- ***Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.***
- ***Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.***

POLICY STATEMENT:

I. Based upon our criteria and assessment of peer-reviewed literature, percutaneous posterior tibial nerve stimulation has been medically proven effective and is considered **medically appropriate** as a treatment modality for patients with voiding dysfunction who meet ALL the following criteria:
   A. Failure of conservative behavioral therapies of at least 3 months duration; AND
   B. Failure of pharmacological therapy that includes at least 2 anticholinergic medications and/or smooth muscle relaxants OR patient has a contraindication to pharmacological therapy.

II. Based upon our criteria and assessment of peer-reviewed literature, percutaneous posterior tibial nerve stimulation has not been medically proven to be effective and is considered **investigational** for all other uses, including, but not limited to: voiding dysfunction due to a neurological condition, constipation, fecal incontinence and chronic pelvic pain.

Refer to Corporate Medical Policy #1.01.19 regarding Pelvic Floor Stimulation as a Treatment for Urinary Incontinence.

Refer to Corporate Medical Policy #7.01.10 regarding Sacral Nerve Stimulation.

Refer to Corporate Medical Policy #8.01.08 regarding Extracorporeal Magnetic Innervation.

POLICY GUIDELINES:

I. Treatment sessions of 12 weekly office visits are considered medically appropriate. Then, once monthly maintenance therapy will be considered if the patient has exhibited at least a 50% improvement in voiding symptoms (based on documentation such as patient voiding diaries) after the initial 12 sessions. Maintenance therapy is also dependent on documentation of a continued treatment response.

II. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Percutaneous posterior tibial nerve stimulation (PPTNS) is an office-based procedure that utilizes electrical neuromodulation in the treatment of voiding dysfunction in patients who have failed conservative therapies (e.g., behavioral, pharmacological). Voiding dysfunction includes urinary frequency, urgency, incontinence, and nonobstructive retention and is usually initially treated with behavioral interventions and/or medications such as anticholinergics. Behavioral therapies include (but are not are not limited to) fluid management, bladder training/timed voiding, and physiotherapy.

The procedure for PPTNS consists of the insertion of a needle above the medial malleolus into the posterior tibial nerve followed by the application of low-voltage (10mA, 1–10 Hz frequency) electrical stimulation that produces sensory and motor responses (e.g., a tickling sensation and plantar flexion or fanning of all toes). The recommended course of treatment is an initial series of 12 weekly office-based treatments followed by an individualized maintenance treatment schedule.

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. Altering the function of the posterior tibial nerve with posterior tibial nerve stimulation (PPTNS) is believed to improve voiding function and control.

Noninvasive PTNS has also been delivered with surface electrodes (transcutaneous posterior tibial nerve stimulation or TPTNS). TPTNS is not addressed in this medical policy.

RATIONALE:

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

Two randomized controlled trials evaluating percutaneous tibial nerve stimulation for treating patients diagnosed with overactive bladder syndrome have been published. In 2009, Peters and colleagues published an industry-sponsored non-blinded comparison of PTNS and extended-release tolterodine (Detrol LA) in women with overactive bladder syndrome (the OrBIT trial). The study included 100 patients (50 per group). A total of 87 of the 100 (87%) of patients completed the study and voiding diary data were available for 84 patients, 41 of 50 (82%) in the PTNS group and 43 of 50 (86%) in the tolterodine group. The primary outcome was the non-inferiority of PTNS in the mean reduction in the number of voids per 24 hours after 12 weeks of treatment. Non-inferiority was defined as no more than a 20% difference in the mean void reduction. Study findings showed non-inferiority of PTNS based on results for 84 patients. The study also reported a number of secondary outcomes and findings on these were mixed. There were no statistically significant differences in the PTNS and tolterodine groups for other symptoms recorded in the voiding diary; this includes mean change in episodes of nocturia, episodes of moderate to severe urgency per day and episodes of urge incontinence per day. In other secondary outcomes, 35 of 44 patients (79.5%) in the PTNS group and 23 of 42 (54.8%) in the tolterodine group reported symptom improvement or cure. This difference was statistically significant (p=0.01), favoring the PTNS group. However, the proportion of patients reporting symptom improvement (excluding the 3 patients reporting that they were cured) did not differ significantly between groups, 34 of 44 (77.3%) of those receiving PTNS and 21 of 42 (50%) receiving tolterodine. Limitations of the OrBIT trial included the lack of blinding of patients and providers, and the lack of comparative data beyond the end of the initial 12-week treatment period.

The second randomized controlled trial, also industry-sponsored, was published by Peters and colleagues in 2010 (SUmiT trial). The eligibility criteria included a score of at least 4 on the overactive bladder questionnaire (OAB-q) short form for urgency, self-report bladder symptoms lasting at least 3 months, and having failed conservative care. A total of 220 patients were randomized, 110 to the PTNS group and 110 to the sham group. Both groups received 12 weekly 30-minute intervention sessions. The 12-week course of treatment was completed by 103 of 110 (94%) in the PTNS group and 105 of 110 (95%) in the sham group. The primary study outcome was response to treatment based on a single-item global response assessment (GRA). The proportion of patients who responded to treatment based on the GRA (i.e., answered that symptoms were moderately or markedly improved) was 60 of 110 (54.5%) in the PTNS group and 23 of 110 (20.9%) in the sham group; this difference was statistically significant, p<0.001. Intention-to-treat analysis was used for the primary endpoint only. Several secondary outcomes also favored the PTNS group. The mean reduction in a symptom severity score (a lower score indicates less severity) was 36.7 in the PTNS group and 29.2 in the sham group, p=0.01. Similarly, the mean reduction in a quality of life scale, the SF-36 (a higher score indicates higher quality of life), was 34.2 in the PTNS group and 20.6 in the sham group, p=0.006. A limitation to this study was that the primary outcome, the GRA, was a single-item subjective measure. In addition, the SUmiT trial only reported comparative data immediately following the initial course of treatment; the study did not evaluate the long-term effectiveness of PTNS. Unlike medication which can be taken on an ongoing basis, PTNS involves an initial 12-week course of treatment followed by maintenance therapy, which to date has not been well-defined. Therefore, the assumption cannot be made that short-term treatment effects will be maintained.

In 2010, MacDiarmid and colleagues reported 1-year follow-up data for patients from the OrBIT trial who had been assigned to the PTNS group and had responded to the initial course of treatment, defined as reporting symptom improvement at 12 weeks. Thirty-three of the 35 responders were included. They received a mean of 12.1 (SD=4.9) treatments between the 12-week and 12-month visits, and there was a median of 17 days between treatments. Data were available for 32 of the 33 (97%) participants at 6 months and 25 of the 33 (76%) participants at 12 months. The mean reduction in number of voids per day from baseline (the original primary outcome of the study) was 3.2 (SD=3.7) at 6 months and 2.8 (SD=3.7) at 12 months. Other voiding diary outcomes at 12 months, based on 25 responses, were mean changes in nocturia episodes of -0.8, in episodes of moderate to severe urgency per day of -3.7 and in episodes of urge incontinence per day of -1.6. As noted above, this analysis was limited in that no data from the tolterodine group were available to compare long-term outcomes. Another limitation was that only PTNS responders were included, rather than all of the patients assigned to PTNS treatment.

Prior to publication of the 2 randomized controlled trials (RCTs) in patients with overactive bladder syndrome, several case series were published. One study, published in 2006 by van der Pal and colleagues, analyzed quality of life questionnaires from 29 patients who were treated with PTNS (3 times per week for 4 weeks) for urge urinary incontinence. At least 12 of the subjects had either no change or an increase in the number of pads used. Another study, published in 2007, assessed the efficacy of 12 weekly sessions of PTNS in 15 patients with chronic pelvic pain. The investigators found subjective improvements in VAS pain scores (8.1 to 4.1) and VAS urgency (4.5 to 2.7), with no change in the number of voids or bladder volume.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

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

HCPCS:	No specific HCPCS codes	
ICD9:	788.20-.29	Urinary retention code range
	788.30-.39	Urinary incontinence code range
	788.41	Urinary frequency
	788.63	Urinary urgency
ICD10:	N39.41-N39.498	Other specified urinary incontinence (code range)
	R33.0-R33.9	Retention of urine (code range)
	R35.0	Frequency of micturition
	R39.15	Urgency of urination

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* key article

KEY WORDS:

Percutaneous/peripheral posterior tibial nerve stimulation, PTNS, SANS, Stoller afferent stimulation

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) and related article for posterior tibial nerve stimulation. Please refer to the following LCD websites for Medicare Members:
http://apps.ngsmedicare.com/lcd/LCD_L31391.htm
http://apps.ngsmedicare.com/sia/ARTICLE_A50267.htm