I. Description

Posterior tibial nerve stimulation (PTNS) 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 limited to) fluid management, bladder training/timed voiding, and physiotherapy.

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 (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). 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 individual 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 stimulation (PTNS) is believed to improve voiding function and control.

II. Criteria/Guidelines

A. The initial 12 week trial for posterior tibial nerve stimulation is covered for the treatment of urinary urgency, urinary frequency, and urge incontinence (subject to Limitations and Administrative Guidelines) when all of the following criteria are met:

1. Failure of conservative behavioral therapies such as bladder training/timed voiding, fluid management and dietary changes, for at least 3 month duration; and

2. Failure of pharmacological therapy that includes at least 2 anticholinergic medications and/or smooth muscle relaxants or patient has a medical contraindication to pharmacological therapy. Medication failure is defined as anaphylaxis, intolerable Posterior Tibial Nerve Stimulation 2 anticholinergic side effects.
effects, or no improvement in symptoms after one month of continuous treatment per medication.

B. Continuation of treatment beyond 12 weeks is covered (subject to Limitation and Administrative Guidelines) when the following criteria are met:
   1. The above criteria for initial trial are met; and
   2. There is documented improvement in symptoms.

III. Limitations
Posterior tibial nerve stimulation is not covered for any other indications including, but not limited to the following because it is not known to be effective in improving health outcomes:
   A. Constipation
   B. Fecal incontinence; and
   C. Chronic pelvic pain

IV. Administrative Guidelines
   A. Precertification is required for an initial trial of 12 weeks. Complete HMSA’s Precertification Request form and fax or mail the form as indicated. The following documentation from the patient’s medical records must be submitted:
      1. Current history and physical documenting the patient’s condition; and
      2. Documentation of behavioral and pharmacological therapies failed.
   B. Precertification is required for continuation up to an additional 24 months of therapy. Complete HMSA’s Precertification Request form and fax or mail the form as indicated. Documentation from the patient’s medical records supporting improvements in symptoms must be submitted.

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>64566</td>
<td>Posterior tibial neurostimulation, percutaneous needle electrode,</td>
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<tr>
<td>ICD-10-CM codes</td>
<td>Description</td>
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<tr>
<td>N39.41-N39.498</td>
<td>Other specified urinary incontinence (code range)</td>
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<tr>
<td>R35.0</td>
<td>Frequency of micturition</td>
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<tr>
<td>R39.15</td>
<td>Urgency of urination</td>
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V. 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 Stroller 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 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 to 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.

VI. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that
HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VII. **References**