MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Tibial Nerve Stimulation (TNS) for Voiding Dysfunction**
Policy Number	**8.01.22**
Category	**Technology Assessment**
Original Effective Date	**03/17/11**
Committee Approval Date	**03/15/12, 03/21/13, 03/20/14, 03/19/15, 03/17/16, 04/20/17, 04/19/18, 04/18/19, 06/18/20, 04/15/21, 04/21/22, 04/20/23, 04/18/24**
Current Effective Date	**04/18/24**
Archived Date	**N/A**
Archive Review Date	**N/A**
Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, percutaneous posterior tibial nerve stimulation (PPTNS) has been medically proven to be effective and, therefore, is considered **medically appropriate** as a treatment modality for patients with urinary urge incontinence, nonobstructive urinary retention, or overactive bladder (OAB) symptoms who meet **BOTH** of the following criteria:
   A. Failure of conservative behavioral therapies of at least three months' duration; **and**
   B. Failure of pharmacological therapy **OR** patient has a contraindication to pharmacological therapy. For urinary urge incontinence and OAB, that includes at least two (2) anticholinergic or beta-3 adrenergic agonist medications and/or smooth muscle relaxants.

II. Based upon our criteria and assessment of the peer-reviewed literature, Tibial Nerve Stimulation (TNS) has not been medically proven to be effective and, therefore, is considered **investigational** for all other uses, including, but not limited to **ALL** of the following:
   A. Voiding dysfunction due to a neurological condition;
   B. Constipation;
   C. fecal incontinence (FI);
   D. chronic pelvic pain.

III. Based upon our criteria and assessment of the peer-reviewed literature, implanted TNS has not been medically proven to be effective and, therefore, is considered **investigational** for all indications.

Refer to Corporate Medical Policy #1.01.55 Electrical Stimulation as a Treatment for Pain and Other Medical Conditions

Refer to Corporate Medical Policy #1.01.19 Pelvic Floor Electrical Stimulation as a Treatment for Urinary or Fecal Incontinence

Refer to Corporate Medical Policy #7.01.10 Sacral Nerve Stimulation

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

POLICY GUIDELINE

Twelve weekly office visits for PPTNS treatment sessions 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.

DESCRIPTION

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 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 PPTNS is believed to improve voiding function and control.

PPTNS has also been proposed as treatment for individuals with non-neurogenic and neurogenic bladder syndromes and fecal incontinence.

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

The eCoin Peripheral Neurostimulator (Valencia Technologies Corporation) is a coin-sized leadless stimulator that is implanted subcutaneously using local anesthetic in the lower leg and delivers 30-minute treatments without the need for users to manipulate to deliver stimulation. It received FDA approval on March 1, 2022. The device is indicated for the treatment of urgency urinary incontinence in individuals who are intolerant to or having an inadequate response to other more conservative treatments who have undergone a successful trial of PPTNS.

RATIONALE

In July 2005, the Urgent PC Neuromodulation System (Uroplasty, Inc.) received Section 510(k) marketing clearance from the FDA for PPTNS to treat patients suffering from urinary urgency, urinary frequency, and urge incontinence. In 2010, the cleared indication was changed to overactive bladder (OAB) and associated symptoms of urinary urgency, urinary frequency, and urge incontinence. The Urgent PC Neuromodulation System is not FDA-cleared for other indications, such as the treatment of fecal incontinence.

The American Urological Association and the Society of Urodynamics, Female Pelvic Medicine &Urogenital Reconstruction (2020) published updated guidelines on the diagnosis and treatment of non-neurogenic overactive bladder in adults. The guidelines included a statement that clinicians may offer PTNS as a third-line treatment option in carefully selected patients. The statement carried a grade C rating, indicating that the balance of benefits and risks/burdens are uncertain.

The American Gastroenterological Association (2017) issued an expert review and clinical practice update on surgical interventions and device-aided therapy for the treatment of fecal incontinence. The update stated that "until further evidence is available, percutaneous tibial nerve stimulation should not be used for managing FI in clinical practice."

Peters and colleagues published an industry sponsored RCT in 2010 (SUmiT trial). The eligibility criteria included a score of at least four on the overactive bladder questionnaire (OAB-q) short form for urgency, self-reported bladder symptoms

lasting at least three months, and failure of conservative care. A total of 220 patients were randomized, 110 to the PPTNS 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 PPTNS 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 PPTNS 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 PPTNS group. The mean reduction in a symptom severity score (a lower score indicates less severity) was 36.7 in the PPTNS 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 PPTNS 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 PPTNS. Unlike medication, which can be taken on an ongoing basis, PPTNS 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 one-year follow-up data for patients from the OrBIT trial who had been assigned to the PPTNS 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, with a median of 17 days between treatments. Data were available for 32 of the 33 (97%) participants at six 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 six 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 PPTNS responders were included, rather than all of the patients assigned to PPTNS treatment.

The evidence for using PPTNS in individuals with fecal incontinence includes several RCTs and systematic reviews. The available RCTs have not found a clear benefit of PPTNS. Neither of the sham-controlled trials found that active stimulation was superior to sham for achieving the primary outcome, at least a 50% reduction in mean weekly fecal incontinence episodes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. There are currently no PPTNS devices cleared by the FDA for the treatment of fecal incontinence.

Zyczynski et al. (2022) conducted the Neuromodulation for Accidental Bowel Leakage (NOTABLe) sham-controlled trial of PTNS in women with fecal incontinence (N=166). Women with greater than or equal to three months of moderate-to-severe fecal incontinence were randomized to PTNS (n=111) or sham stimulation (n=55). Stimulation was delivered in 12 weekly 30-minute sessions to a single lower extremity. The primary outcome was change from baseline in St. Mark score (a 7-item, validated patient-reported outcome) measured after 12 weekly treatments. Secondary outcomes included stool consistency, bowel movement, and stool leakage episodes per week. There was no significant difference between the PTNS group (-5.3 points) and the sham group (-3.9 points) in terms of improvement from baseline in St. Mark scores (adjusted difference -1.3;95% CI, -2.8 to 0.2). There also was no significant difference in reduction in weekly fecal incontinence episodes from baseline between the PTNS group (-2.1 episodes) and sham group (-1.9 episodes) (adjusted difference -0.26; 95% CI, -1.85 to 1.33).

Implantable Peripheral Neurostimulators for the Treatment of Voiding Dysfunction*:*
Approval for the eCoin Peripheral Neurostimulator was granted based on a prospective, open-label, multi-site, single arm clinical trial (NCT03556891) of 132 individuals. The primary outcome of the interventional study was the percentage of individuals experiencing 50% or better improvement in urgency urinary incontinence episodes after subcutaneous stimulation of the tibial nerve using the eCoin device, as measured by a 3-day voiding diary capturing the number of Urgency Incontinence Episodes/day, voids per/day, urgency episodes/day, nocturia episodes/day as well as quality of life (via Overactive Bladder Questionnaire). All individuals were successfully implanted with the device. Data was collected at baseline and the primary outcome was assessed at 48 weeks after device activation. Device activation occurred 4

weeks after implantation. The analysis demonstrated 68% of the individuals were considered responders, experiencing a 50% or better improvement in their symptoms. Measured at 52 weeks post-implantation, 17/133 (12.78%) had experienced an adverse event, which mostly consisted of skin infection (3.01%) and issues with the device itself (14.7%) such as a stimulation issue, device dislocation, or device malfunction. The study was funded by the vendor, was unblinded, without a comparator group and limited length of follow-up. Studies with longer-term follow up and sound methodology are needed.

CODES

- *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.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming
64590	Insertion or replacement of peripheral, sacral or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
0587T **(E/I)**	Percutaneous implantation or replacement of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve
0588T **(E/I)**	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve
0589T **(E/I)**	Electronic analysis with simple programming of implanted integrated neurostimulation system (e.g., electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, posterior tibial nerve, 1-3 parameters
0590T **(E/I)**	Electronic analysis with complex programming of implanted integrated neurostimulation system (egg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, posterior tibial nerve, 4 or more parameters
0816T **(E/I)**	Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (e.g., array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subcutaneous *(effective 01/01/24)*
0817T **(E/I)**	when performed, posterior tibial nerve; subfascial *(effective 01/01/24)*
0818T **(E/I)**	Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subcutaneous (*effective 01/01/24)*
0819T **(E/I)**	when performed, posterior tibial nerve; subfascial *(effective 01/01/24)*

HCPCS Codes

Code	Description
No specific HCPCS codes	

ICD10 Codes
Medically Appropriate Codes:

Code	Description
N32.81	Overactive bladder
N39.41	Urge incontinence
R35.0	Frequency of micturition
R35.81	Nocturnal polyuria
R35.89	Other polyuria
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) for posterior tibial nerve stimulation (L33396). Please refer to the following LCD websites for Medicare Members: [https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33396&ver=10&CntrctrSelected=298*1&Cntrctr=298&name=National+Government+Services%2c+Inc.+(13201%2c+A+and+B+and+HHH+MAC%2c+J+-+K)&s=All&DocType=Active&bc=AggAAAQBAAAA&] accessed 03/08/24.