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# Clinical Policy Title: Posterior tibial neurostimulation treatment for urine leakage

## **Policy contains:** Acupuncture; percutaneous tibial neurostimulation.; overactive bladder stimulation

About this policy: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Select Health of South Carolina when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Select Health of South Carolina's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Select Health of South Carolina's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies are not guarantees of payment.

## Coverage policy

Posterior tibial neurostimulation treatment is clinically proven and, therefore, medically necessary for overactive bladder, when the following criteria are met:

- Overactive bladder symptoms have existed for at least three months.
- After behavioral therapy (first-line therapy) has been tried and failed, or when members are unwilling or unable to comply with behavioral therapy regimens and instructions.
- Failure or experience of adverse events with one medication have been followed by an attempt with at least one other medication (which also failed or adverse effects were experienced) (Gormley, 2019).

A total of 12 weekly treatments are considered necessary for initial treatment. If successful, continued monthly treatments can also be considered necessary (Gormley, 2019), at a frequency of every one to two months for the remainder of a year (Centers for Medicare & Medicaid Services, Local Coverage Determination L33406).

## Limitations

If the member fails to respond after the initial six treatments, continued treatment is considered investigational and not medically necessary (Centers for Medicare & Medicaid Services, Local Coverage Determination L33406).

All other uses of posterior tibial neurostimulation for overactive bladder syndrome are considered investigational and not medically necessary.

## Alternative covered services

Behavioral and pharmaceutical therapy (as first- and second-line therapies), and sacral neuromodulation or onabotulinumtoxinA (as other third-line therapies).

## Background

Overactive bladder syndrome, defined as urgency to void, usually with accompanying frequency and nocturia, with or without urge urinary incontinence, in the absence of urinary tract infection or other obvious pathology, is a common condition in adults and children. Causes are multiple, although there is some evidence that genetic predisposition may be one factor (de Wall, 2017).

Several types of neuromodulation, including sacral nerve stimulation and posterior tibial neurostimulation, are used as (non-first-line) treatments for overactive bladder syndrome. Neuromodulation is defined as the effect of cross-signaling between sympathetic and parasympathetic postganglionic nerve terminals and synapses, altering nerve signals involved in the voiding reflex (Groat, 2015).

Peripheral neurostimulation, including posterior tibial neurostimulation, is derived from traditional Chinese medicine, or acupuncture. A commonly used acupuncture point is San-Yin-Jiao, or Spleen 6 (SP-6), on the medial side of the lower leg. The location of the SP-6 point and the organs affected by its stimulation are similar to posterior tibial neurostimulation treatment for overactive bladder syndrome (de Wall, 2017).

The technique uses a 34 gauge needle electrode inserted 4 cm - 5 cm cephalad to the medial malleolus to stimulate the nerve. After current is applied, the flexion of the big toe or the movement of the other toes confirms the correct positioning of the needle electrode. The electric current is a continuous, square wave form with a duration of 200  $\mu$ s and a frequency of 20 Hz. The intensity is determined by the highest level tolerated by the patient (Gaziev, 2013).

The first mention in the literature of using posterior tibial neurostimulation for overactive bladder syndrome discovered that 87 percent of 22 patients with the syndrome experienced partial or total improvement (McGuire, 1983). The commonly used time interval of 12 weeks to determine efficacy and safety was a result of clinical trials (Peters, 2010).

In October 2010, the U.S. Food and Drug Administration approved the Urgent<sup>®</sup> PC Neuromodulation System (Uroplasty, Inc., Minnetonka Minnesota) for overactive bladder syndrome (U.S. Food and Drug Administration, 2010). In November 2013, the Food and Drug Administration approved the NURO<sup>™</sup> Neuromodulation System (Advanced Uro-Solutions, Suwanee Georgia) for overactive bladder syndrome, but not other disorders (U.S. Food and Drug Administration, 2013).

Data from the International Continence Society showed a sharp increase in the number of third-line procedures for overactive bladder syndrome from 2010 to 2013 (n = 1822 to 6143), before leveling off in the succeeding two years at 5340 and 5946 (Drangsholt, 2019).

## dFindings

The 2019 updated guideline of the American Urological Association/Society of Urodynamics and Female Urology on overactive bladder considers behavioral therapies as first-line treatment because they can resolve some cases while presenting essentially no risks to the patient. The guideline recommended pharmacology therapies as second-line treatment for patients unwilling or unable to comply with behavioral therapy regimens and instructions. Third-line therapies, including posterior tibial neurostimulation treatment, can be considered after failure or an adverse event for at least two medications (Gormley, 2019).

Systematic reviews have been published in the professional literature, with the following findings:

- Posterior tibial neurostimulation treatment improved symptoms in about 60 percent of the patients (47 percent to 56 percent) in the long run, much greater than the estimated placebo effect of 21 percent, in addition to not being costly but it was time-consuming (de Wall, 2017).
- Twenty-one reports compared sacral neuromodulation with percutaneous tibial nerve stimulation for patients
  with lower urinary tract dysfunction. Per-study ranges of improvement >50 percent was observed in the sacral
  group (29 percent to 76 percent) and the percutaneous group (54 percent to 59 percent), with percutaneous
  patients showing fewer side effects. Authors conclude percutaneous tibial nerve stimulation is a less invasive
  technique that is effective and safe, but has not been tested in the long term (Tutolo, 2018).
- Sixteen trials, 11 randomized, of adults with overactive bladder syndrome included a meta-analysis of four studies of percutaneous tibial nerve stimulation versus sham procedures. Compared to sham, the percutaneous group had an overall risk ratio of 7.32, borderline significant at *P* = .09 (Wibisono, 2015).
- Of 16 studies (n = 469) of patients with neurogenic lower urinary tract dysfunction, only four were randomized and controlled. In both acute and chronic tibial nerve stimulation, increases were observed for maximum cystometric capacity, and bladder volume at first detrusor overactivity. Decreases were observed in maximum detrusor pressure during the storage phase, number of voids per 24 hours, number of leakages per 24 hours, along with increases for postvoid residual (Schneider, 2015).
- Of 32 studies (n = 1087), 16 addressed overactive bladder syndrome (640 treated, 189 controls). A total of 59 percent of patients treated with percutaneous tibial nerve stimulation responded positively, leading authors to conclude the therapy is effective and safe for overactive bladder syndrome (Gaziev, 2013).
- Ten studies, four of which were randomized, included adults with overactive bladder syndrome. Strong evidence showed percutaneous tibial nerve stimulation to be more effective than sham treatment, while limited evidence showed it to be as effective as tolterodine (extended-release) (Moosdorff-Steinhauser, 2013).
- Ten studies evaluating treatment of overactive bladder syndrome with percutaneous tibial nerve stimulation revealed success rates from 37 percent to 82 percent (total 61.4 percent). Four randomized trials showed the treatment was significantly more effective than sham, while two others showed no difference in outcomes with antimuscarinic medication. Authors recommend more long-term studies (Burton, 2012).

- In 73 studies of lower urinary tract dysfunction, implanted sacral nerve stimulation, percutaneous posterior tibial nerve stimulation, and transcutaneous electrical stimulation therapy modalities were compared.
   Reductions in incontinence for the sacral nerve and percutaneous tibial nerve approaches were similar, but more long-term follow-up studies for the latter are needed (Monga, 2012).
- A review of overactive bladder syndrome in women identified 17 articles, only four of which used high-quality data. A range of 54 percent to 93 percent success in reducing symptoms were reported for all studies (Levin, 2012).

Tibial nerve stimulation can also be used transcutaneously for overactive bladder syndrome, in addition to percutaneously. A systematic review of 13 studies (n = 629), 10 of them randomized, showed transcutaneous nerve stimulation to be significantly more effective than sham, and similar to antimuscarinic treatment, in reducing overactive bladder symptoms, without adverse events. Authors recommend that this limited evidence be expanded (Booth, 2018).

A cost-effectiveness study of various treatments of refractory overactive bladder determined that onabotulinumtoxinA was superior to implantable sacral nerve stimulation devices, percutaneous tibial nerve stimulation, anticholinergic medications, and mirabegron compared with best supportive care for management of refractory overactive bladder (Murray, 2019).

A cost comparison of percutaneous tibial nerve stimulation and sacral stimulation were similar for initial 12 weekly treatments (\$1,773 versus \$1,857 per patient). Cumulative discounted two-year costs of ongoing therapy, including those who discontinued therapy, were much lower for the percutaneous group (\$3,850 versus \$14,160), due largely to the sacral nerve stimulation surgical implant, which cost \$22,970 each (Martinson, 2013).

# Billing and coding

Below are National Coverage Determinations, Local Coverage Determinations, and the most commonly submitted codes subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate Centers for Medicare & Medicaid Services references and coding manuals, and bill accordingly.

## National coverage determinations

No National Coverage Determinations were identified as of the writing of this policy.

## Local coverage determinations

L33406 Posterior tibial nerve stimulation (PTNS).

L33443 Posterior tibial nerve stimulation (PTNS) for urinary control.

L33396 Posterior tibial nerve stimulation (PTNS) for voiding control.

L35011 Surgery: posterior tibial nerve stimulation (PTNS) for urinary control.

## ICD-10 diagnosis codes

N13.81-Overactive Bladder N39.41-Urge Incontinence N39.46-Mixed Incontinence N39.492-Postural (urinary) incontinence N39.498-Other specified urinary incontinence R32-Unspecified urinary incontinence R35.0-Frequency of micturition R39.15-Urgency of urination

## CPT procedure codes

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

HCPCS level II codes

N/A

## Policy updates

None.

## References

On April 30, 2019, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were "percutaneous," "posterior," "tibial nerve stimulation," and "transcutaneous." We included the best available evidence according to established evidence hierarchies (typically systematic reviews, metaanalyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Moossdorff-Steinhauser HF, Bereghmans B. Effects of percutaneous tibial nerve stimulation on adult patients with overactive bladder syndrome: a systematic review. *Neurourol Urodyn*. 2013;32(3):206-214. Doi: 10.1002/nau.22296.

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## Appendix

No additional information was identified for this section during the writing of this policy.