

## Corporate Medical Policy

# Percutaneous Tibial Nerve Stimulation for Voiding Dysfunction

<b>File Name:</b>	percutaneous_tibial_nerve_stimulation_for_voiding_dysfunction
<b>Origination:</b>	1/2007
<b>Last CAP Review:</b>	11/2020
<b>Next CAP Review:</b>	11/2021
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### Description of Procedure or Service

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Percutaneous tibial nerve stimulation (PTNS; also known as posterior tibial nerve stimulation) is a technique of electrical neuromodulation used primarily for the treatment of voiding dysfunction in patients who have failed behavioral therapies and/or pharmacologic therapies. Voiding dysfunction includes urinary frequency, urgency, incontinence and nonobstructive retention. Common causes of non-neurogenic voiding dysfunction are pelvic floor neuromuscular changes (from pregnancy, childbirth, surgery, etc.), inflammation, medication side effects (e.g., diuretics and anticholinergics), obesity, and psychogenic factors. Overactive bladder is a non-neurogenic voiding dysfunction characterized by urinary frequency, urgency, urge incontinence, and nonobstructive retention.

Neurogenic bladder dysfunction is caused by neurologic damage in patients with multiple sclerosis, spinal cord injury, detrusor hyperreflexia, or diabetes with peripheral nerve involvement. The symptoms include overflow incontinence, frequency, urgency, urge incontinence, and retention.

Approaches to the treatment of incontinence differentiate between urge incontinence and stress incontinence. Conservative behavioral management such as lifestyle modification (e.g., dietary changes, weight reduction, fluid management, smoking cessation) along with pelvic floor exercises and bladder training are part of the initial treatment of overactive bladder symptoms and both types of incontinence. Pharmacotherapy is another option, and different medications target different symptoms. Some individuals experience mixed incontinence.

If behavioral therapies and pharmacotherapy are unsuccessful, percutaneous tibial nerve stimulation (PTNS), sacral nerve stimulation, or botulinum toxin may be recommended.

The current U.S. Food and Drug Administration (FDA)-cleared indication for PTNS is overactive bladder (OAB) and associated symptoms of urinary urgency, urinary frequency, and urge incontinence.

Altering the function of the posterior tibial nerve with PTNS is believed to improve voiding function and control. The mechanism of action is believed to be retrograde stimulation of the lumbosacral nerves (L4- S3) via the posterior tibial nerve located near the ankle. The lumbosacral nerves control the bladder detrusor and perineal floor.

The system used to provide PTNS consists of a small gauge needle electrode, surface electrode, lead wire, and handheld external electrical generator. The percutaneous needle is inserted just above the ankle with a surface electrode on the arch of the foot. After the lead wire and electrode

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are attached, the electrical generator is used to stimulate the tibial nerve. This stimulation inhibits bladder activity and evokes a central inhibition of the micturition reflex pathway in the spinal cord or the brain. Noninvasive PTNS has also been delivered with surface electrodes. PTNS studies have been designed using 30-minute sessions given weekly for 10-12 weeks. Recently, consideration has been given to increasing the frequency of treatments to 3 times per week to speed achievement of desired outcomes. However, an optimal treatment approach has not been identified and the durability or long term benefit of PTNS is uncertain.

PTNS must be distinguished from acupuncture with electrical stimulation. In electrical acupuncture, needles are also inserted just below the skin, but the placement of needles is based on specific theories regarding energy flow throughout the human body. Thus in PTNS, the location of stimulation is directly in the posterior tibial nerve rather than using the theories of energy flow that guide placement of stimulation for acupuncture.

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. In 2010, the cleared indication was changed to "overactive bladder (OAB) and associated symptoms of urinary urgency, urinary frequency, and urge incontinence." The NURO™ Neuromodulation System (Advanced UroSolutions, now Medtronic) was cleared by FDA in November 2013. The Urgent PC Neuromodulation System and the NURO™ Neuromodulation System are not FDA-cleared for other indications, such as the treatment of fecal incontinence.

There is developing wireless technology for the treatment of overactive bladder, approved in Europe. BlueWind (BlueWind Medical) is a wireless, battery-less, miniature implantable neurostimulator that is activated by an external device worn at the ankle.

PTNS was derived as a less-invasive treatment alternative to traditional sacral root neuromodulation which has been successfully used in the treatment of urinary dysfunction, but requires implantation of a permanent device. In sacral root neuromodulation, an implantable pulse generator that delivers controlled electrical impulses is attached to wire leads that connect to the sacral nerves, most commonly the S3 nerve root that modulates the neural pathways controlling bladder function.

PTNS is not cleared by FDA for treating fecal incontinence; however, the treatment has been proposed for this purpose. The manufacturer recommends a course of treatment for fecal incontinence similar to the one used to treat OAB; an initial course of 12 weekly sessions of tibial nerve stimulation followed by a personalized schedule of follow-up treatments.

## Related Policies:

Pelvic Floor Stimulation as a Treatment of Urinary Incontinence

Sacral Nerve Neuromodulation/Stimulation for Pelvic Floor Dysfunction

***\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

## **Policy**

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# Percutaneous Tibial Nerve Stimulation for Voiding Dysfunction

**BCBSNC will provide coverage for percutaneous tibial nerve stimulation when it is determined to be medically necessary because the medical criteria and guidelines noted below are met.**

## Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

## When Percutaneous Tibial Nerve Stimulation for Voiding Dysfunction is covered

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Percutaneous tibial nerve stimulation may be considered medically necessary in patients with nonneurogenic overactive bladder syndrome who meet the following criteria:

- 1) Symptoms of overactive bladder syndrome for at least 3 months duration AND
- 2) Failed behavioral therapies (e.g., pelvic floor muscle training, biofeedback, timed voids and/or fluid management) AND
- 3) Failed pharmacological therapy that includes at least 2 anticholinergic medications and/or smooth muscle relaxants OR patient has a contraindication to pharmacological therapy.

If the criteria are met, a total of 12 treatments (one per week) will be initially approved.

Maintenance therapy using monthly percutaneous tibial nerve stimulation is considered medically necessary for individuals following a 12-week initial course of percutaneous tibial nerve stimulation that resulted in improved urinary dysfunction meeting treatment goals.

## When Percutaneous Tibial Nerve Stimulation for Voiding Dysfunction is not covered

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Percutaneous tibial nerve stimulation is considered investigational in all other situations not described above.

## Policy Guidelines

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For individuals who have non-neurogenic urinary dysfunction including overactive bladder who have failed behavioral and pharmacologic therapy who receive an initial course of PTNS, the evidence includes randomized sham-controlled trials, randomized controlled trials (RCTs) with an active comparator, and systematic reviews. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The Sham Effectiveness in Treatment of Overactive Bladder Symptoms and the Overactive Bladder Innovative Therapy trials are two key industry-sponsored RCTs. Systematic reviews that include these trials and other published trials have found short-term improvements with PTNS. The largest, highest quality study was the double-blinded, sham-controlled Sham Effectiveness in Treatment of Overactive Bladder Symptoms trial. It reported a statistically significant benefit of PTNS vs. sham at 12 weeks. In an additional small sham-controlled trial, a 50% reduction in urge incontinent episodes was attained in 71% of PTNS group compared with 0% in the sham group.

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The nonblinded Overactive Bladder Innovative Therapy trial found that PTNS was noninferior to medication treatment at 12 weeks. Adverse events were limited to local irritation effects. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have overactive bladder syndrome that has failed behavioral and pharmacologic therapy who respond to an initial course of PTNS who receive maintenance PTNS, the evidence includes observational studies and systematic reviews. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The Sham Effectiveness in Treatment of Overactive Bladder Symptoms and the Overactive Bladder Innovative Therapy trials each included extension studies that followed individuals who responded to the initial course of PTNS and continued to receive periodic maintenance therapy. There is variability in the interval between and frequency of maintenance treatments, and an optimal maintenance regimen remains unclear. There are up to 36 months of observational data available, reporting that there is a durable effect for some of these patients. While comparative data are not available after the initial 12-week treatment period, the observational data support a clinically meaningful benefit for use in individuals who have already failed behavioral and pharmacologic therapy and who respond to the initial course of PTNS. PTNS may allow such individuals to avoid more invasive interventions. Adverse events appear to be limited to local irritation for both short and long-term PTNS use. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have neurogenic bladder dysfunction who receive PTNS, the evidence includes several RCTs and a systematic review of RCTs and observational data. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Only a few RCTs evaluating tibial nerve stimulation for treating neurogenic bladder have been published to date, and all but one performed transcutaneous stimulation rather than PTNS. Studies varied widely in factors, such as the study populations and comparison interventions. Study findings have not reported that tibial nerve stimulation significantly reduced incontinence symptoms and improved other outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have fecal incontinence who receive PTNS, the evidence includes several RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The available RCTs have not found a clear benefit of PTNS. 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 larger sham-controlled randomized trial did find a significantly greater decrease in the absolute number of weekly incontinence episodes in the active treatment group, but the overall trial findings did not suggest the superiority of PTNS over sham treatment. A meta-analysis of a single RCT and several observational studies reported that patients receiving sacral nerve stimulation experienced significant benefits compared with patients receiving PTNS. A post hoc analysis of the larger trial suggested a subset of patients with fecal incontinence (those without concomitant obstructive defecation) may benefit from PTNS. The evidence is insufficient to determine the effects of the technology on health outcomes.

## **Billing/Coding/Physician Documentation Information**

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

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*Applicable service codes: 0587T, 0588T, 0589T, 0590T, 64566*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources

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External Specialty Matched Consultant review 4/4/06

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Specialty Matched Consultant Advisory Panel review 5/8/07.

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Specialty Matched Consultant Advisory Panel 11/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.106, 8/13/2020

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Specialty Matched Consultant Advisory Panel 11/2020

## Policy Implementation/Update Information

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- 1/3/07 Notification of new policy. BCBSNC will not provide coverage for posterior tibial nerve stimulation for urinary dysfunction, including but not limited to urinary frequency, urgency, incontinence and retention, because it is considered investigational. BCBSNC does not cover investigational services. Notification given 1/3/07. Effective date 3/12/07. (pmo)
- 6/4/07 Specialty Matched Consultant Advisory Panel review 5/8/07. No changes to criteria. Reference source added. (pmo)
- 9/28/09 No changes to criteria. Repeated same types of urinary dysfunction under "When not Covered" that is included in policy statement. Reference sources added. (pmo)
- 6/22/10 Policy Number(s) removed (amw)
- 1/18/11 Specialty Matched Consultant Advisory Panel review 12/2010. Policy Guidelines updated. References updated. Added CPT code 64566 and deleted CPT code 64999. Added "overactive bladder syndrome" to the Policy statement as well as to the "When not covered" section. (mco)
- 12/20/11 Specialty Matched Consultant Advisory Panel review 11/2011. References updated. BCBSA 2010 TEC Assessment information added to Policy Guidelines. No changes to Policy Statement. (mco)
- 3/20/12 References updated. Policy Guidelines updated. No changes to policy statement. (mco)
- 7/24/12 References updated. Added "neurogenic bladder" to "When not Covered" section. Specific clinical conditions deleted from Policy Statement. Revised Policy Statement: "BCBSNC will not provide coverage for posterior tibial nerve stimulation because it is considered investigational. BCBSNC does not cover investigational services." Medical Director review 7/2012. (mco)
- 1/15/13 Added "Related Policies" to the Description section. Specialty Matched Consultant Advisory Panel review 11/2012. No changes to Policy Statement. (mco)
- 7/16/13 Policy Guidelines updated. References updated. Medical Director review 6/2013. (mco)
- 12/10/13 Specialty Matched Consultant Advisory Panel review 11/2013. Medical Director review 11/2013. References updated. No changes to Policy Statements. (mco)
- Policy titled Percutaneous Tibial Nerve Stimulation for Voiding Dysfunction"**
- 4/1/16 Title changed to Percutaneous Tibial Nerve Stimulation. "Posterior" changed



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to “percutaneous” in existing policy statement. Medical Policy Statement revised to state: “BCBSNC will provide coverage for percutaneous tibial nerve stimulation when it is determined to be medically necessary because the medical criteria and guidelines noted below are met.” “When Covered” section revised to state: “Percutaneous tibial nerve stimulation may be considered medically necessary in patients with nonneurogenic overactive bladder syndrome who meet the following criteria: 1) Symptoms of overactive bladder syndrome for at least 3 months duration AND 2) Failed behavioral therapies (e.g., pelvic floor muscle training, biofeedback, timed voids and/or fluid management), AND 3) Failed pharmacological therapy that includes at least 2 anticholinergic medications and/or smooth muscle relaxants OR patient has a contraindication to pharmacological therapy. If the criteria are met, a total of 12 treatments (one per week) will be initially approved. Patients who experience improvement in their OAB symptoms after the 12 initial treatments may receive on-going treatments every 3 weeks (every 1 to 2 months) for up to one year. Treatments after 12 months are considered experimental/investigational.” “When not Covered” section revised to state: “Percutaneous tibial nerve stimulation is considered investigational in all other situations not described above. Treatments after 12 months are considered experimental/investigational.” Policy Guidelines updated. References updated. Medical Director review 11/2015. Policy noticed on 4/1/16 for effective date 5/31/16. (mco/sk)

- 1/27/17 Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 11/30/2016. (sk)
- 7/13/18 Specialty Matched Consultant Advisory Panel review 11/29/2017. Reference added. Coverage criteria for maintenance therapy added to Policy Statement. Policy Guidelines updated. (sk)
- 12/14/18 Description and Policy Guidelines updated. Reference added. Specialty Matched Consultant Advisory Panel review 11/28/2018. (sk)
- 10/29/19 Reference added. (sk)
- 12/10/19 Specialty Matched Consultant Advisory Panel review 11/20/2019. (sk)
- 1/14/20 CPT codes 0587T, 0588T, 0589T, and 0590T added to Billing/Coding section. (sk)
- 5/4/21 Reference added. Specialty Matched Consultant Advisory Panel review 11/18/2020. (sk)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.