MASSACHUSETTS

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Medical Policy

Percutaneous and Subcutaneous Tibial Nerve Stimulation

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Policy Number: 583

BCBSA Reference Number: 7.01.106 (For Plan internal use only)

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Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Percutaneous tibial nerve stimulation for an initial 12-week course* is considered **MEDICALLY NECESSARY** for individuals with non-neurogenic urinary dysfunction including overactive bladder who have **both**:

- failed behavioral therapy following an appropriate duration of 8 to 12 weeks without meeting treatment goals; **and**
- failed pharmacologic therapy following 4 to 8 weeks of treatment without meeting treatment goals.

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.

*Management criteria would be **once-per-week for 12 weeks and once-per-month afterward for maintenance treatments**.

*Annual evaluation by a physician may be performed to ensure efficacy is continuing for maintenance percutaneous tibial nerve stimulation treatments.

Percutaneous tibial nerve stimulation is considered **INVESTIGATIONAL** for all other indications, including but not limited to the following:

- Neurogenic bladder dysfunction
- Fecal incontinence.

Subcutaneous tibial nerve stimulation delivered by an implantable peripheral neurostimulator system (e.g., eCoin) is considered **INVESTIGATIONAL** for all indications, including individuals with non-neurogenic urinary dysfunction including overactive bladder.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** if the procedure is performed inpatient.

Outpatient

- For services described in this policy, see below for situations where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **not required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

CPT Codes

CPT codes:	Code Description
0587T	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	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	Electronic analysis with simple programming of implanted integrated neurostimulation system (eg, 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	Electronic analysis with complex programming of implanted integrated neurostimulation system (eg, 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

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

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT codes above if <u>medical necessity criteria</u> are met:

ICD-10 Diagnosis Coding

ICD-10-CM-diagnosis codes:	Code Description
N32.81	Overactive bladder
N39.41	Urge incontinence
N39.42	Incontinence without sensory awareness
N39.43	Post-void dribbling
N39.44	Nocturnal enuresis
N39.45	Continuous leakage
N39.46	Mixed incontinence
N39.490	Overflow 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

The following CPT code is considered investigational for <u>Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:</u>

HCPCS Codes

HCPCS codes:	Code Description
E0736	Transcutaneous tibial nerve stimulator

Description

Voiding Dysfunction

Common causes of non-neurogenic voiding dysfunction are pelvic floor neuromuscular changes (eg, from pregnancy, childbirth, surgery), inflammation, medication (eg, diuretics, 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.

Treatment

Approaches to the treatment of incontinence differentiate between urge incontinence and stress incontinence. Conservative behavioral management such as lifestyle modification (eg, 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.

Percutaneous Tibial Nerve Stimulation
The current indication cleared by the U.S. Food and Drug Administration (FDA) for PTNS is overactive bladder and associated symptoms of urinary frequency, urinary urgency, 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.

Administration of PTNS consists of inserting a needle above the medial malleolus into the posterior tibial nerve followed by the application of low-voltage (10 mA, 1-10 Hz frequency) electrical stimulation that produces sensory and motor responses as evidenced by a tickling sensation and plantarflexion or fanning of all toes. Noninvasive PTNS has also been delivered with transcutaneous or surface electrodes. The recommended course of treatment is an initial series of 12 weekly office-based treatments followed by an individualized maintenance treatment schedule.

Percutaneous tibial nerve stimulation is less invasive than traditional sacral nerve neuromodulation (see evidence review 7.01.69), which has been successfully used to treat 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.
Percutaneous tibial nerve stimulation has also been proposed as a treatment for non-neurogenic and neurogenic bladder syndromes and fecal incontinence.

Subcutaneous Tibial Nerve Stimulation
The current indication approved by the FDA for subcutaneous tibial nerve stimulation (STNS) is urgency urinary incontinence in individuals who are intolerant or who have had an inadequate response to more conservative treatments or who have undergone a successful trial of PTNS. STNS is administered through a coin-sized leadless battery-powered implant (see Regulatory section). STNS offers a less invasive alternative to traditional sacral nerve neuromodulation and offers a convenient delivery system for automated treatments without the need for chronic outpatient PTNS treatment sessions.

Summary
Description
Percutaneous tibial nerve stimulation (PTNS; also known as posterior tibial nerve stimulation) is an electrical neuromodulation technique used primarily for treating voiding dysfunction. Subcutaneous tibial nerve stimulation via an implantable peripheral neurostimulator is an alternate technique for treating urgency urinary incontinence associated with overactive bladder syndrome.

Summary of Evidence
For individuals who have non-neurogenic urinary dysfunction including overactive bladder and have failed behavioral and pharmacologic therapy who receive an initial course of percutaneous tibial nerve stimulation (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 (SUmiT) and the Overactive Bladder Innovative Therapy (OrBIT) trials are 2 key industry-sponsored RCTs. Systematic reviews that included these and other published trials have found short-term reductions in voiding dysfunction with PTNS. The largest, highest quality study was the double-blind, sham-controlled SUmiT trial, which reported a statistically significant benefit of PTNS versus sham at 12 weeks. In an additional, small sham-controlled trial, a 50% reduction in urge incontinent episodes was attained in 71% of the PTNS group compared with 0% in the sham group. The nonblinded OrBIT trial found that PTNS was noninferior to medication therapy at 12 weeks. Adverse events were limited to local irritation effects. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have overactive bladder syndrome that have failed behavioral and pharmacologic therapy who respond to an initial course of PTNS and 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 SUmiT and OrBIT 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. Percutaneous tibial nerve stimulation 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. Typical regimens schedule maintenance treatments every 4-6 weeks. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have non-neurogenic urinary dysfunction including overactive bladder and who have failed behavioral and pharmacologic therapy or who have responded to an initial course of PTNS and then receive subcutaneous tibial nerve stimulation (STNS), the evidence includes single-arm studies. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The pivotal open-label, single-arm study leading to FDA-approval of the subcutaneously-implanted, wireless eCoin tibial nerve stimulation system demonstrated a 68% response rate at 48 weeks of follow-up which surpassed a performance goal of 40%. However, the certainty of the evidence is limited by the lack of comparator group and a lower response rate observed during the COVID-19 pandemic. Additionally, the FDA noted that the performance goal was identified after patients had already been implanted. An ongoing post-approval study may elucidate the certainty of benefit, including safety of reimplantation given battery lifespan concerns. The evidence is insufficient to determine that the technology results in an 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 1 performed transcutaneous stimulation rather than PTNS. Studies varied widely in factors such as study populations and comparator interventions. Study findings have not reported that tibial nerve stimulation significantly reduced incontinence symptoms and improved other outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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. None of the sham-controlled trials found that active stimulation was superior to sham for achieving a 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. An additional sham-controlled randomized trial did not identify a benefit of PTNS over sham stimulation. 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 that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
4/2024	Clarified coding information.

1/2024	Annual policy review. References added. Investigational policy statement added for subcutaneous tibial nerve stimulation delivered by an implantable peripheral neurostimulator system for all indications, including individuals with non-neurogenic urinary dysfunction including overactive bladder. Title updated. Effective 1/1/2024.
10/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
9/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
10/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
1/2020	Clarified coding information.
10/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
9/2018	Annual policy review. New medically necessary indications described. Prior Authorization Information reformatted. Clarified coding information. Effective 9/1/2018.
3/2016	Annual policy review. New references added.
6/2015	Annual policy review. New investigational indications described. Effective 6/1/2015.
1/2015	Clarified coding information.
9/2014	New indications for coverage for Medicare HMO and PPO Blue. Effective 8/10/2014.
4/2014	Annual policy review. New references added.
11/2013	Not medically necessary indications described for Medicare HMO and PPO Blue. Effective 10/25/2013. Removed ICD-9 diagnosis codes 596.51, 788.31, 788.33, 788.34, 788.39, 788.41, 788.63, changed LCD to L31391 as L31523 is no longer effective and changed prior authorization information for Medicare HMO and PPO Blue as 64566 is not covered per LCD: L31391.
6/2013	Annual policy review. New references added.
2/2013	Annual policy review. New investigational indications described. Effective 2/4/2013.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
9/2011	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
4/2011	Annual policy review. No changes to policy statements.
1/19/2011	New policy describing covered and non-covered indications. Effective 1/19/2011,.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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