BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 7.01.106 Percutaneous and Subcutaneous Tibial Nerve Stimulation

Annual Effective Policy Date: January 1, 2024

Original Policy Date: December 2012

Related Policies:

1.01.17 - Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence
7.01.19 - Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence
7.01.29 - Percutaneous Electrical Nerve Stimulation, Percutaneous Neuromodulation Therapy, and Restorative Neurostimulation Therapy

Percutaneous and Subcutaneous Tibial Nerve Stimulation

Description

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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.

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.

OBJECTIVE

The objective of this evidence review is to determine whether the use of percutaneous or subcutaneous tibial nerve stimulation improves the net health outcome in individuals who have urinary dysfunction associated with overactive bladder syndrome, neurogenic bladder, or fecal incontinence.

POLICY STATEMENT

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.

Percutaneous tibial nerve stimulation is considered **investigationa**l 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.

POLICY GUIDELINES

Individuals may be considered to have failed behavioral therapies following an appropriate duration of 8 to 12 weeks without meeting treatment goals.

Individuals may be considered to have failed pharmacologic therapies following 4 to 8 weeks of treatment without meeting treatment goals.

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

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

In 2005, the Urgent PC Neuromodulation System was the initial PTNS device cleared for marketing by the FDA through the 510(k) process to treat patients suffering from urinary urgency, urinary frequency, and urge incontinence. Additional PTNS devices have been cleared for marketing through the 510(k) process. They are listed in Table 1.

The devices are not FDA cleared for other indications, such as the treatment of fecal incontinence.

Wireless technology is evolving for the treatment of overactive bladder. In March 2022, the eCoin Peripheral Neurostimulator System (Valencia Technologies Corporation) became the first subcutaneous tibial nerve stimulation implant approved by the FDA through the premarket authorization (PMA) process for individuals with urgency urinary incontinence (P200036; FDA Product Code: QPT).

Table 1. FDA-Cleared Percutaneous Tibial Nerve Stimulators (FDA Product Code: NAM)

Device Name	Manufacturer	Cleared	510(k)	Indications
Urgent PC Neuromodulation System	Uroplasty, now Cogentix Medical	Oct 2005	K052025	Treatment of urinary urgency, urinary frequency, and urge incontinence
Urgent PC Neuromodulation System	Uroplasty, now Cogentix Medical	Jul 2006	K061333	FDA determined the 70% isopropyl alcohol prep pad contained in the kit is subject to regulation as a drug
Urgent PC Neuromodulation System	Uroplasty, now Cogentix Medical	Aug 2007	K071822	Labeling update, intended use is unchanged
Urgent PC Neuromodulation System	Uroplasty, now Cogentix Medical	Oct 2010	K101847	Intended use statement adds the diagnosis of overactive bladder
NURO™ Neuromodulation System	Advanced Uro-Solutions, now Medtronic	Nov 2013	K132561	Treatment of patients with overactive bladder and associated symptoms of urinary urgency, urinary frequency, and urge incontinence
ZIDA Wearable Neuromodulation System	Exodus Innovations	Mar 2021	K192731	Treatment of patients with an overactive bladder and associated symptoms of urinary urgency, urinary frequency, and urge incontinence

FDA: U.S. Food and Drug Administration.

RATIONALE

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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Urological Association et al

In 2019, the American Urological Association and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction published updated guidelines on the diagnosis and treatment of non-neurogenic overactive bladder in adults.[50,] 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.

American College of Obstetricians and Gynecologists

In 2015, the American College of Obstetricians and Gynecologists practice bulletin on the treatment of urinary incontinence in women did not address PTNS or other types of nerve stimulation.[51,]

American Gastroenterological Association

In 2017, the American Gastroenterological Association issued an expert review and clinical practice update on surgical interventions and device-aided therapy for the treatment of fecal incontinence.[52,] The update stated that "until further evidence is available, percutaneous tibial nerve stimulation should not be used for managing FI [fecal incontinence] in clinical practice."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2012	New policy	
September 2013	Replace policy	Policy updated with literature review. References 5, 6, 8-10, 12-15, 17 and 20 added; other references renumbered or removed. Policy statement unchanged.
September 2014	Replace policy	Policy updated with literature review; reference 1 added, 5 updated; policy statement unchanged.
September 2015	Replace policy	Policy updated with literature review; Title changed to "Percutaneous Tibial Nerve Stimulation., "Posterior, changed to "percutaneous, in existing policy statement. Policy statement edited to not medically necessary for all indications with bullet points for urinary and fecal incontinence. Reference 17-19 added.
June 2016	Replace policy	Policy updated with literature review through November 30, 2015; references 15, 17, 19-25, 27-28, and 30-31 added. Policy statements unchanged.
June 2018	Replace policy	Policy updated with literature review through September 15, 2017; reference 18 added; reference 31 updated. Revised policy statements for use of PTNS in OAB syndrome that has failed behavioral and pharmacologic therapy. In these patients, PTNS is considered medically necessary as an initial course of therapy and maintenance therapy for individuals who respond to initial course. Percutaneous tibial nerve stimulation changed from not medically necessary to investigational (due to FDA 510k approval status) for all other indications, including but not limited to the following: Neurogenic bladder dysfunction; Fecal incontinence.
December 2018		Policy updated with literature review through June 4, 2018; references 13-14, 27, 32, 34, and 37 added. Policy statements are unchanged.
December 2019	Replace policy	Policy updated with literature review through May 31, 2019; references added. Policy statements unchanged.
December 2020	Replace policy	Policy updated with literature review through May 28, 2020; references added. Policy statements unchanged.
December 2021	Replace policy	Policy updated with literature review through June 24, 2021; references added. Policy statements unchanged.
December 2022	Replace policy	Policy updated with literature review through June 28, 2022; references added. Minor editorial refinements to policy statements; intent unchanged.
December 2023	Replace policy	Policy updated with literature review through June 28, 2023; 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.