02.01.78 Percutaneous and Implantable Posterior Tibial Nerve Stimulation

Original Effective Date: September 2010

Review Date: September 2025

Revised: September 2025

DISCLAIMER/INSTRUCTIONS FOR USE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations, or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

Related Policies:

- 02.01.73 Biofeedback as a Treatment of Urinary Incontinence
- 02.01.75 Artificial Urinary Sphincter
- 02.01.76 Periurethral Bulking Agents for the Treatment of Stress Urinary Incontinence
- 02.01.77 Periurethral Bulking Agents for the Treatment of Vesicoureteral Reflux
- 02.01.79 Miscellaneous Investigational Therapies and Tests for the Treatment of Urinary Incontinence/Urinary Dysfunction
- 08.01.21 - Sacral Nerve Neuromodulation/Stimulation

Summary

Description

Posterior tibial nerve stimulation (PTNS; also known as posterior tibial nerve stimulation) is an electrical neuromodulation technique used primarily for treating voiding dysfunction. 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 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 percutaneous PTNS. The largest, highest quality study was the double-blind, sham-controlled SUmiT trial, which reported a statistically significant benefit of percutaneous 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 percutaneous PTNS group compared with 0% in the sham group. The nonblinded OrBIT trial found that percutaneous 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 has failed behavioral and pharmacologic therapy who respond to an initial course of percutaneous PTNS and who receive maintenance percutaneous 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 percutaneous 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 percutaneous PTNS. Percutaneous 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 percutaneous 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 implantable PTNS, 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 implantable, 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 percutaneous 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 percutaneous 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.

Additional Information

2018 Input

Clinical input was sought to help determine whether the use of maintenance PTNS for individuals with non-neurogenic urinary dysfunction including overactive bladder who have failed behavioral and pharmacologic therapy and respond to an initial course of PTNS would provide a clinically meaningful improvement in the net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 3 physician respondents identified by specialty societies.

For individuals with non-neurogenic urinary dysfunction including overactive bladder who have failed behavioral and pharmacologic therapy and respond to an initial course of PTNS, clinical input supports this use provides a clinically meaningful improvement in net health outcome and indicates this use is consistent with generally accepted medical practice.

Further details from clinical input are included in the Appendix.

OBJECTIVE

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

PRIOR APPROVAL

Not applicable.

POLICY

Medically Necessary

Percutaneous posterior tibial nerve stimulation (PTNS) for an initial 12-week course may be considered **medically necessary** for individuals with non-neurogenic urinary dysfunction including overactive bladder (OAB) (see Policy Guidelines) who have **all of the following**:

- 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 PTNS may be considered **medically necessary** for individuals who meet **all of the following**:

- a 12-week initial course of posterior tibial nerve stimulation that resulted in improved urinary dysfunction meeting treatment goals.

Investigational

Percutaneous PTNS not meeting the above criteria and for all other indications including but not limited to neurogenic bladder dysfunction is considered **investigational** because the evidence is insufficient to determine the technology results in an improvement in the net health outcomes.

An implantable PTNS delivered by a peripheral neurostimulator system (e.g., eCoin) is considered **investigational** for all indications, including but not limited to non-neurogenic urinary dysfunction (see Policy Guidelines) including overactive bladder because the evidence is insufficient to determine the technology results in an improvement in the net health outcomes.

ALL Category III codes will be considered **investigational** unless the code is explicitly addressed as a covered service in a Wellmark BlueCross BlueShield Medical Coverage Policy.
***Note**: For Posterior tibial nerve stimulation (PTNS) for the treatment of fecal incontinence see medical policy 02.01.51 Fecal Incontinence Management.*

POLICY GUIDELINES

Annual evaluation by a physician may be performed to ensure efficacy is continuing for maintenance posterior tibial nerve stimulation (PTNS), but this is not required for continued approval if the criteria above has been met.

Definitions

Non-Neurogenic Voiding Dysfunction: Common causes of non-neurogenic voiding dysfunction are pelvic floor neuromuscular changes (e.g., from pregnancy, childbirth, surgery), inflammation, medication (e.g., 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 - 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.

Coding

See the Codes table for details.

Category III codes are a set of temporary (T) codes for emerging technologies, services, and procedures that allow for data collection by the American Medical Association's (AMA). If a Category III code is available, providers must use that code instead of an unlisted or deleted Category I code. The services or procedures represented by Category III codes may not have FDA approval, may not be performed by many health care professionals across the country, and the service or procedure may not have proven clinical efficacy. Certain T codes may be addressed as a covered service in a Wellmark BlueCross BlueShield Medical Coverage Policy. But, unless there is explicit Policy criteria that specifically extends coverage to a particular Category III code, the code would generally be considered experimental, investigational, or unproven.

BACKGROUND

Voiding Dysfunction

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

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, 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.

Implantable Tibial Nerve Stimulation

The current indication approved by the FDA for subcutaneous tibial nerve stimulation (STNS) also known as implantable tibial nerve stimulation 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.

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.

Wireless technology is evolving for the treatment of overactive bladder In March of 2022, the FDA approved 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). Bluewind's Revi is also now FDA approved as of August of 2023 which also stimulated the posterior tibial nerve for individuals with urge incontinence and an overactive bladder.

Table 1. FDA-Cleared Percutaneous Posterior 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

Device Name	Manufacturer	Cleared	510(k)	Indications
Altaviva™ Implantable Tibial Neuromodulation System	Medtronic	Sept 2025	P240011	Treatment of urge urinary incontinence in patients who failed or could not tolerate more conservative treatments.

FDA: U.S. Food and Drug Administration.

RATIONALE

This evidence review was created in September 2010 with searches of the PubMed database. The most recent literature update was performed through August 19, 2025.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Percutaneous Tibial Nerve Stimulation for Non-Neurogenic Urinary Dysfunction Including Overactive Bladder

Clinical Context and Therapy Purpose

The purpose of percutaneous posterior tibial nerve stimulation (PTNS) in individuals who have non-neurogenic urinary dysfunction including overactive bladder (OAB) and have failed behavioral and pharmacologic therapy or those with OAB who have responded to an initial course of PTNS, is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant populations of interest are:

- Individuals who have non-neurogenic urinary dysfunction including OAB who have failed behavioral and pharmacologic therapy, and
- Individuals with OAB responsive to an initial course of percutaneous PTNS.

Interventions
The therapy being considered is PTNS as an initial or maintenance therapy. During PTNS, a needle is inserted above the medial malleolus into the posterior tibial nerve followed by the application of low-voltage (10 mA, 1-10 Hz frequency) electrical stimulation. Noninvasive PTNS may be 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.

Comparators
The following therapies are currently being used to make decisions about non-neurogenic urinary dysfunction: botulinum toxin and sacral nerve stimulation (SNS).

Botulinum toxin is injected into the detrusor muscle. However, the toxin increases the risk of urinary retention and is not recommended for patients with a history of urinary retention or recurrent urinary tract infection (UTI).

Sacral nerve stimulation may be conducted in an outpatient clinical setting using temporary wire leads. Due to the incidence of lead migration, a 2-step process in a surgical setting is recommended. In the initial test phase, wire leads are inserted under the skin and if 50% improvement is reported, the patient may elect permanent implantation with a pacemaker-like stimulator. If the test phase is unsuccessful, the leads are then removed.

Outcomes
The general outcomes of interest are reductions in symptoms (e.g., self-reported assessment of symptoms, decrease in the number of voids per day) and improved quality of life. Outcomes are measured following the 12-week treatment regimen.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews
Wang et al (2020) evaluated PTNS for patients with OAB in a systematic review and meta-analysis that included 28 studies (N=2,461). The efficacy of PTNS was compared to baseline information before treatment or other treatments (not specified). Reviewers included several trials discussed in the sections below: the Overactive Bladder Innovative Therapy (OrBIT) trial (Peters et al [2009]), the Sham Effectiveness in Treatment of Overactive Bladder Symptoms (SUmiT) trial (Peters et al [2010]), and the Finazzi-Agro et al (2010), Vecchioli-Scaldazza et al (2013), and Preyer et al (2015) trials. Results demonstrated that PTNS reduced the daily frequency of the following symptoms: voiding (mean difference [MD], −2.48; 95% confidence interval [CI, −3.19 to −1.76), nocturia (MD, −1.57; 95% CI, –2.16 to −0.99), urgency episodes (MD, −2.20; 95% CI, –3.77 to −0.62), and incontinence episodes (MD, −1.37; 95% CI, –1.71 to −1.02). Percutaneous tibial nerve stimulation also improved maximum cystometric capacity (MD, 63.76; 95% CI, 31.90 to 95.61) and compliance (MD, 7.62; 95% CI, 0.61 to 14.63). The

pooled success rate was 68% (95% CI, 59% to 78%). The most common complication following PTNS was pain at the puncture site.

Xiong et al (2021) performed a systematic review with meta-analysis of 6 RCTs (N=291) evaluating the efficacy of tibial nerve stimulation (either PTNS or transcutaneous tibial nerve stimulation [TTNS]) versus anticholinergic medications for OAB. The SUmIT trial and trials by Vecchioli-Scaldazza et al (2013) and Preyer et al (2015) were among those included. There was a significant reduction in urge incontinence episodes with tibial nerve stimulation versus anticholinergic medications (MD, -1.11; 95% CI, -1.66 to -0.55). However, tibial nerve stimulation and anticholinergic medications had comparable effects on micturition, nocturia, urgency, and voided volume. Discontinuation due to adverse events was lower with tibial nerve stimulation than with anticholinergic medications (odds ratio [OR], 0.13; 95% CI, 0.03 to 0.51).

Two systematic reviews that did not include a quantitative analysis evaluated PTNS for nonobstructive urinary retention. Coolen et al (2020) evaluated 8 studies, 5 of which reported the efficacy of PTNS and 2 that of transcutaneous electrical nerve stimulation (TENS). The objective success rate for PTNS (defined as a decrease of at least 50% in the frequency or volume of catheterization per 24 hr) was 25% to 41%. The subjective success rate (defined as the patient's request for continued chronic treatment with PTNS) ranged from 25% to 41%. A subjective success rate of 80% was reported in 1 study of women who received transvaginal TENS. Ho et al (2021) evaluated 16 studies, 5 of which reported on the efficacy of PTNS and 11 that of sacral neuromodulation (also referred to as SNM).The success rate for PTNS (defined as at least a 50% reduction in symptoms) ranged from 50% to 60%, while the success rates for SNM (which had variable definitions across trials) ranged between 42.5% and 100% (median, 79.2%) for the test stimulation phase and 65.5% to 100% (median, 89.1%) in the long term (median follow, 42 months).

Tutulo et al (2018) searched the literature through December 2017 and identified 21 studies using either SNS or PTNS to treat lower urinary tract dysfunction and chronic pelvic pain not responding to standard therapies. Reviewers concluded that both SNS and PTNS were effective therapies. Percutaneous tibial nerve stimulation demonstrated higher success rates (≥50% reduction in leakage episodes) and fewer side effects compared with SNS; however, longer follow-up studies with PTNS are needed. Another systematic review by Tutulo et al (2018) conducted a literature search through December 2017 of RCTs evaluating SNS and PTNS for the treatment of OAB unresponsive to standard medical therapy. Five RCTs were identified. Reviewers concluded that both SNS and PTNS, with success rates ranging from 61% to 90% and 54% to 79%, respectively, could be considered effective.

A Cochrane review by Stewart et al (2016) evaluated electrical stimulation with nonimplanted electrodes for OAB in adults. The literature search was current up to December 2015. The objective of the review was to determine whether electrical stimulation (including vaginal and rectal electrical stimulation, and PTNS) was better than no treatment or better than any other treatment available for OAB. Studies reviewed were RCTs or quasi-RCTs of electrical stimulation that included adults with OAB with or without urgency and urge urinary incontinence. Trials whose participants had stress urinary incontinence were excluded. Sixty-three eligible trials were identified (N=4424 randomized participants). Reviewers included several trials discussed below: the OrBIT (Peters et al [2009]) and OrBIT follow-up trials (MacDiarmid et al [2010]), the SUmiT trial (Peters et al [2010]), the Sustained Therapeutic Effects of Percutaneous Tibial Nerve Stimulation (STEP) trial (Peters et al [2013]), and the Finazzi-Agro et al (2010), Schreiner et al (2010), Vecchioli-Scaldazza et al (2013), and Preyer et al (2015) trials.

Data were obtained from the end of treatment and the longest available follow-up period. The primary outcomes identified were the perception of cure, the perception of improvement, and condition-related quality of life measures as defined by the original authors or by any validated measurement scales such

as the International Consultation on Incontinence Questionnaire. Secondary outcomes pertinent to the evidence review were a quantification of symptoms, procedure outcome measures, and adverse events.

The key findings from the Cochrane review (2016) of evidence are summarized in Table 2. Percutaneous tibial nerve stimulation results were combined for vaginal and rectal electrical stimulation.

Table 2. Summary of Cochrane Systematic Review Outcomes

Comparators to Electrical Stimulation[a]	Electrical Stimulation Effect[a]	QOE
No active treatment, placebo, or sham		
Reduction in OAB symptoms	More effective	Moderate
Reduction in urge urinary incontinence	More effective	Moderate
Improvement in OAB-related quality of life	More effective	Moderate
Pelvic floor muscle training		
Reduction in OAB symptoms	More effective	Moderate
Reduction in urge urinary incontinence	Effect uncertain	No evidence
Improvement in OAB-related quality of life	Effect uncertain	Low
Drug therapy		
Reduction in OAB symptoms	More effective	Moderate
Reduction in urge urinary incontinence	Effect uncertain	No evidence
Improvement in OAB-related quality of life	Effect uncertain	No evidence
Oxybutynin or tolterodine		
Adverse events	Lower risk	Low
Placebo/sham		
Adverse events	Lower risk	Moderate

Adapted from Stewart et al (2016)
OAB: overactive bladder; QOE: quality of evidence.
[a]Electrical stimulation includes percutaneous tibial nerve stimulation.

Forty-four trials did not report the primary outcomes of perception of cure or improvement in OAB. The majority of trials were deemed to be at low or unclear risk of selection and attrition bias and unclear risk of performance and detection bias. Lack of clarity regarding the risk of bias was largely due to poor reporting. Many studies did not report whether electrical stimulation was safer than other treatments or if one type of electrical stimulation was safer than others.

This review was informed by a TEC Assessment (2013) evaluating PTNS as a treatment for voiding dysfunction. It concluded that PTNS as a treatment for voiding dysfunction met TEC criteria and showed that PTNS improves the net health outcome. Specifically, PTNS ameliorated symptoms of chronic OAB or urinary voiding dysfunction, simultaneously improving quality of life parameters among patients who have failed behavioral and pharmacologic therapies.

In this assessment of 6 RCTs, TEC reviewers drew the following conclusion about the evidence:

"Evidence from randomized placebo-controlled trials supports the clinical efficacy of PTNS applied in the standard 12-week regimen. No concurrently controlled evidence exists from a trial over longer periods of time in maintenance therapy. Although the lack of controlled evidence on maintenance PTNS raises concern about whether short-term efficacy is maintained over the long term, the available 12- to 36-month evidence appears consistent with maintained efficacy in relieving symptoms of OAB and urinary voiding dysfunction. Adverse event rates, assuming accurate ascertainment, appear limited."

In 2012 and 2013, several other systematic reviews of the literature on PTNS for treating OAB were published. Only one conducted pooled analyses of study results. This review, by Burton et al (2012), conducted a pooled analysis of data from 4 trials (2 of which were abstracts) comparing PTNS with sham treatment. Reviewers found a significantly higher risk of successful treatment with PTNS (relative risk [RR], 7.02; 95% CI, 1.69 to 29.17) compared with a control intervention. The CI was wide, indicating a lack of precision in the pooled estimate. The patient samples in these studies were homogenous by sex, severity and duration of symptoms, and previous treatment history. The definition of successful treatment also varied among studies. The SUmiT trial (discussed below) contributed 220 (76%) of 289 patients in the pooled analysis.

Also, Shamliyan et al (2012) conducted a comparative effectiveness review for the Agency for Healthcare Research and Quality on the broader topic of nonsurgical treatments for urinary incontinence in adult women. Reviewers identified 4 RCTs comparing PTNS with no active treatment in patients with OAB. Two of the 4 RCTs reported 12-week results of the sham-controlled SUmiT trial; 1 of them included a subgroup of SUmiT participants and was only published as an abstract. The Shamliyan report included a pooled analysis of data from 3 studies that found a statistically significant improvement in urinary incontinence in the PTNS group compared with the control group (RR, 1.9; 95% CI, 1.1 to 3.2). This pooled analysis included 405 patients: 220 in the SUmiT trial, 150 in the SUmiT trial subgroup analysis, and 35 in a trial by Finazzi-Agro et al (2010). A limit of the Shamliyan et al (2012) analysis was that the 150 patients in the SUmiT subgroup analysis were included twice. The Shamliyan review did not discuss evidence on the efficacy of PTNS beyond 12 weeks.

Sham-Controlled Randomized Trials

The SUmiT trial, reported by Peters et al (2010), was a sham-controlled randomized trial. Before conducting the trial, investigators performed a pilot study in healthy volunteers to determine the adequacy of a sham PTNS intervention. The sham procedure was correctly identified by 10 (33%) of 30 volunteers. This percentage is below the 50% that could be expected by chance, so investigators concluded that the procedure was a feasible sham. Eligibility criteria included: a score of 4 or more on the Overactive Bladder Questionnaire Short Form (OAB-q SF) for urgency, self-reported bladder symptoms lasting at least 3 months, and having failed conservative care for these symptoms or a diagnosis of OAB. Overactive bladder and quality of life questionnaires, as well as 3-day voiding diaries, were completed at baseline and 13 weeks.

Both the randomized sham and active intervention groups received 12 weekly 30-minute intervention sessions. In the sham group, a blunt (placebo) instrument was used to simulate the location and sensation of needle electrode insertion in active treatment. One inactive PTNS surface electrode and 2

active TENS surface electrodes were used. The TENS unit (Urgent PC system) delivered low-level stimulation to mimic the PTNS intervention. The 12-week treatment was completed by 103 (94%) of 110 in the PTNS group and 105 (95%) of 110 in the sham group.

The primary trial endpoint was an efficacy assessment measured by a 7-level global response assessment (GRA) tool, in which patients reported change in symptoms as markedly worse, moderately worse, mildly worse, the same, slightly improved, moderately improved, or markedly improved. A responder was defined as one who reported symptoms as moderately or markedly improved at week 13. The rate of responders was 54.5% (60/110) of PTNS subjects compared with 20.9% (23 of 110) of sham subjects. There was a statistically significant benefit reported with PTNS compared with sham treatment in voiding diary variables as well.

Six PTNS subjects reported 9 mild or moderate treatment-related adverse events consisting of ankle bruising, discomfort at the site of needle insertion, bleeding at the site, and tingling in the leg. No local treatment-related adverse events were reported in the sham group, and no systemic adverse events occurred in either group.

The STEP trial, an extension of the SUmiT study, included only responders from the PTNS group. The purpose was to determine the threshold for maintenance therapy. Of the 60 PTNS group 13-week responders, 50 entered the extension study. Patients underwent a 14-week transitional protocol consisting of 2 treatments with a 14-day interval, 2 treatments with a 21-day interval, and then 1 treatment after another 28 days. Following this 14-week period, a personal treatment plan was developed for each patient. Percutaneous tibial nerve stimulation was delivered when patients reported that their symptoms increased. Between 6 and 36 months, patients received a median of 1.1 monthly PTNS treatments after the 14-week tapering period. Data were available on 34 patients at 24 months and on 29 patients at 36 months. In a per-protocol analysis, compared with baseline, 28 (97%) of 29 patients who completed the 36-month follow-up met the primary efficacy endpoint of moderate or marked improvement in overall bladder symptoms on the GRA. Also, compared with baseline, all voiding diary measures were significantly improved in this group of patients at every 6-month follow-up.

Adverse events noted in the STEP study included 1 report of restricted vaginal opening with unknown relation to treatment and 2 mild bleeding events at the needle site in the same participant. Nine patients reported 11 mild adverse events with an unknown relation to treatment including vaginal bleeding, mild depression, shoulder pain, diarrhea, leg pain, stomachache, pelvic pain, UTI, a pulling sensation in both feet, bladder pressure, and pinched nerve pain.

A limitation of the SUmiT trial was that the primary outcome (the GRA) is a single-item subjective measure. An additional limitation was that only short-term comparative data were available. And unlike medication that can be taken in the same manner on an ongoing basis, PTNS involves an initial 12-week course of treatment followed by maintenance therapy, which varies from the initial treatment course. To date, maintenance therapy has not been well defined.

Tables 3 and 4 summarize the SUmiT RCT and STEP extension studies.

Table 3. Summary of SUmiT RCT and STEP Extension Characteristics

Study; Trial	Countries	Sites	Dates	Randomized or Enrolled/ Completed Trial		Outcome
				PTNS	Sham	
Peters et al (2010); SUmiT	U.S.	23	2008-2009	110/103	110/105	GRA at 13 wk
Peters et al (2013); STEP	U.S.	23	2009-2012	50/29[a]	None	GRA at 36 mo

GRA: global response assessment; PTNS: percutaneous tibial nerve stimulation; RCT: randomized controlled trial; STEP: Sustained Therapeutic Effects of Percutaneous Tibial Nerve Stimulation; SUmiT: Sham Effectiveness in Treatment of Overactive Bladder Symptoms.
[a] Extension study of 50 PTNS responders in SUmiT trial.

Table 4. Summary of SUmiT RCT and STEP Extension Results

Study	Primary Outcome: Moderately or Markedly Improved GRA			
	PTNS, n/N (%)	**Sham, n/N (%)**	**Confidence Intervals**	**p**
SUmiT (2010)				
GRA (13 wk)	60/110 (54.5)	23/110 (20.9)	NR	<.001
STEP (2013)				
GRA (36 mo)	28/29 (97)	None	None	None

GRA: Global response assessment; NR: not reported; PTNS: percutaneous tibial nerve stimulation; RCT: randomized controlled trial; STEP: Sustained Therapeutic Effects of Percutaneous Tibial Nerve Stimulation: SUmiT: Sham Effectiveness in Treatment of Overactive Bladder Symptoms.

An RCT by Finazzi-Agro et al (2010) evaluated 35 women who had urge incontinence and detrusor overactivity on urodynamic testing. Patients were randomized to 30-minute PTNS sessions, 3 times per week for 4 weeks (n=18) or sham treatment (n=17). One patient dropped out of the PTNS group, and 2 dropped out of the sham group; analysis was not intention-to-treat. The primary outcome, percent responders at 4 weeks (defined as at least 50% reduction in incontinent episodes), was attained by 12 (71%) of 17 in the PTNS group and 0 (0%) of 15 in the sham group.

Other Randomized Controlled Trials

An RCT comparing PTNS with medication for the treatment of OAB was published by Vecchioli-Scaldazza et al (2018). This 3-arm trial compared solifenacin (n=27), PTNS (n=34), and a combination of solifenacin plus PTNS (n=33) and followed patients through 10 months post treatment. Patients in all 3 arms experienced significant reductions from baseline in daytime frequency, night-time frequency, and urgency. Percutaneous tibial nerve stimulation was more effective than solifenacin alone, and the combination of PTNS plus solifenacin was more effective than PTNS alone. The combination therapy also showed the longest effect.

A group of RCTs has compared PTNS with an alternative treatment, medication, conservative therapy, or electrical stimulation. The trials reported inconsistent findings on short-term efficacy, and only 1 reported on the efficacy of PTNS beyond 12 weeks.

Three studies used medication as the comparison intervention. Preyer et al (2015) published a nonblinded study comparing 12 weeks of PTNS with tolterodine in 36 women who had OAB. There were no significant differences between groups on the reduction of incontinence episodes in 24 hours (p=.89) or quality of life (p=.07).

Another RCT comparing PTNS with solifenacin was a crossover trial published by Vecchioli-Scaldazza et al (2013). Forty women with OAB received PTNS (twice weekly for 6 weeks) or medication, given in random order, with a 6-week washout period between treatments. Group A received medication first, and group B received PTNS first. The primary efficacy outcome was a reduction in the number of voids in a 24-hour period. Thirty (75%) of the 40 patients completed the trial. The number of daily voids (the primary outcome) significantly decreased after each treatment compared with before treatment. Also, secondary outcomes, including nocturia urge incontinence, and voided volume, significantly improved after each treatment compared with pretreatment values. The authors did not directly compare the efficacy of medication with PTNS.

An RCT compared PTNS with conservative therapy. Schreiner et al (2010) assessed 51 women older than 60 years of age who complained of urge urinary incontinence. Women were randomized to 12 weeks of conservative treatment (Kegel exercises, bladder training) alone (n=26) or conservative treatment plus 12 weekly sessions of PTNS (n=25). Blinding was not discussed. The response rate at 12 weeks, defined as a reduction of at least 50% in the number of incontinence episodes reported by the patient in a bladder diary, was 76% in the PTNS group and 27% in the conservative treatment-only group (p=.001).

Gungor Ugurlucan et al (2013) in Turkey compared transvaginal electrical stimulation (n=38) with PTNS (n=21) in women who had OAB. The electrical stimulation protocol consisted of 20-minute treatments, 3 times a week for 6 to 8 weeks. Percutaneous tibial nerve stimulation was performed with an Urgent PC device used for 12 weekly, 30-minute sessions. Fifty-two (88%) of 59 patients completed the trial. The authors assessed numerous outcome variables and did not specify primary outcomes or adjust p values for multiple comparisons. Four bladder diary variables were reported. From baseline to the end of the treatment period, the groups did not differ significantly in mean change in urgency episodes, nocturia, or incontinence episodes. The mean number of urgency episodes was 2.9 at baseline and 1.6 after treatment in the electrical stimulation group, and 2.0 at baseline and 1.3 after treatment in the PTNS group (p=.54). The mean daytime frequency was 7.8 at baseline and 5.8 after treatment in the electrical stimulation group, and 7.6 at baseline and 7.4 in the PTNS group (p=.03). The authors reported that a significantly higher proportion of patients in the electrical stimulation group described themselves as cured, but they did not provide proportions or p values.

The OrBIT trial is the largest randomized trial that was not sham controlled. This trial was a nonblinded comparison of PTNS and extended-release tolterodine (Detrol LA) in women with OAB. Eligibility included symptoms of OAB, with at least 8 voids per 24 hours; the mean daily voids for those entering the study were 12.3. The primary outcome was the noninferiority of PTNS in the mean reduction in the number of voids per 24 hours after 12 weeks of treatment. Noninferiority was defined as no more than a 20% difference in the mean void reduction. As expected, the mean reduction in voids of 1.8 for tolterodine and 3.6 for PTNS was based on previously published efficacy data. Study findings showed the noninferiority of PTNS based on results for 84 participants.

The trial also reported on secondary outcomes. There were no statistically significant differences between the PTNS and tolterodine groups for other symptoms recorded in the voiding diary. Improvement in all OAB symptom episodes was statistically significant within each group from baseline to 12 weeks, but not between groups.

The OrBIT trial lacked blinding of patients and providers and lacked comparative data beyond the end of the initial 12-week treatment period. There was no sham or placebo group to mitigate the potential bias due to subjective outcomes. Also, the trialists did not clearly define criteria for "improvement" or "cure" (a key secondary outcome) and did not report the extent of compliance with medical therapy. Finally, different data collection methods were used in the 2 groups (eg, for adverse event outcomes and possibly for other self-reported outcomes).

MacDiarmid et al (2010) reported on 1-year follow-up data for patients from the OrBIT trial who had been assigned to the PTNS group and had reported symptom improvement at 12 weeks. Of the 35 responders, 33 were included. They received a mean of 12.1 additional treatments between the 12-week and 12-month visits, and there was a median of 17 days between treatments. Data were available for 32 (97%) of the 33 participants at 6 months and 25 (76%) of the 33 participants at 12 months.

As noted, this analysis lacked data from the tolterodine group to assess long-term outcomes. Additionally, not all patients in the PTNS group were included in the follow-up analysis; rather, only PTNS responders were eligible. A potential bias is that the initial subjective outcome measure might have been subject to the placebo effect. Moreover, patients in the PTNS group who responded to initial treatment might have been particularly susceptible to a placebo response and/or might represent those with the best treatment response. Thus, these individuals might also have been susceptible to a placebo response during maintenance treatments, especially treatments offered on an as-needed basis.

Tables 5 and 6 summarize the OrBIT and OrBIT 1-year follow-up studies.

Table 5. Summary of OrBIT RCT Characteristics

Study	Countries	Sites	Dates	Randomized/Completed		Outcome[a]
				PTNS	Tolterodine	
Peters et al (2009)	U.S.	11	2006-2008	50/41	50/43	Reported
MacDiarmid et al (2010) 1-y follow-up	U.S.	11	2008-2009	33/32[b]		Reported

OrBIT: Overactive Bladder Innovative Therapy, PTNS: percutaneous tibial nerve stimulation; RCT: randomized controlled trial.
[a] Mean reduction in the number of voids per 24 hours after 12 weeks of treatment.
[b]Eligible responders from 12-week study.

Table 6. Summary of OrBIT RCT Results

Study	Primary Outcome: Mean Reduction in Voids per Day (SD)			
OrBIT (2009)	PTNS (n=41)		Tolterodine (n=43)	
	Baseline	12 Weeks	Baseline	12 Weeks

Study	Primary Outcome: Mean Reduction in Voids per Day (SD)			
Voids per day	12.1 (3.1)	-2.4 (4.0)	12.5 (3.7)	-2.5 (3.9)
p		<.001		<.001
Confidence interval		NR		NR
OrBIT 1-y follow-up (2010)	**PTNS (n=25)**			
	Baseline	**12 Months**		
Voids per day	12.4 (3.5)	-2.8 (3.7)	Not applicable	Not applicable
p		<.001		
Confidence interval		NR		

NR: not reported; OrBIT: Overactive Bladder Innovative Therapy, PTNS: percutaneous tibial nerve stimulation; RCT: randomized controlled trial; SD: standard deviation.

Section Summary: Non-Neurogenic Urinary Dysfunction Including Overactive Bladder

Initial Course of Percutaneous PTNS

For individuals who have non-neurogenic urinary dysfunction including OAB who have failed behavioral and pharmacologic therapy and received an initial course of percutaneous PTNS, a number of RCTs of PTNS have been published, including 2 key industry-sponsored RCTs, the OrBIT and SUmiT trials. Systematic reviews of the evidence have found short-term improvements with percutaneous PTNS. The largest, highest quality study was the blinded, sham-controlled SUmiT trial. This trial reported a statistically significant benefit of percutaneous PTNS versus sham at 12 weeks. In another small sham-controlled trial, a 50% reduction in urge incontinent episodes was attained in 71% of the percutaneous PTNS group compared with 0% in the sham group. The nonblinded OrBIT trial found that percutaneous PTNS was noninferior to medication treatment at 12 weeks.

Maintenance Course of Percutaneous PTNS

For individuals who have OAB syndrome who have failed behavioral and pharmacologic therapy, respond to an initial course of percutaneous PTNS, and then receive maintenance percutaneous PTNS therapy, there are up to 36 months of observational data that suggest there is a durable effect for some of these patients. The SUmiT and OrBIT trials each included extension studies, which followed individuals who responded to the initial course of percutaneous 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. 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 respond to the initial course of percutaneous PTNS. Percutaneous 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. Typical regimens schedule maintenance treatments every 4 to 6 weeks.

Implantable Tibial Nerve Stimulation for Non-Neurogenic Urinary Dysfunction Including Overactive Bladder

Clinical Context and Therapy Purpose

The purpose of implantable PTNS in individuals who have non-neurogenic urinary dysfunction including overactive bladder (OAB) with episodes of urgency urinary incontinence and have failed behavioral and pharmacologic therapy or who have responded to an initial course of PTNS is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant populations of interest are:

- Individuals who have non-neurogenic urinary dysfunction including OAB with episodes of urgency urinary incontinence who have failed behavioral and pharmacologic therapy, and
- Individuals with OAB with episodes of urgency urinary incontinence responsive to an initial course of PTNS.

Interventions

The therapy being considered is implantable PTNS. The eCoin Peripheral Neurostimulator System is an FDA-approved coin-sized leadless battery-powered implant that delivers electrical stimulation to the tibial nerve (0.5-15 mA, 20 Hz frequency). The recommended treatment duration is 30 minutes every 3 days for the first 18 weeks (42 session) and every 4 days thereafter and is programmed by the clinician. A patient controller can be leveraged to inhibit an automatic session in the event of undesired or painful stimulation. The battery life is estimated at up to 3 years (range, 1-8 years).

Comparators

The following therapies are currently being used to make decisions about non-neurogenic urinary dysfunction: botulinum toxin and sacral nerve stimulation (SNS):

Botulinum toxin is injected into the detrusor muscle. However, the toxin increases the risk of urinary retention and is not recommended for patients with a history of urinary retention or recurrent urinary tract infection (UTI).

Sacral nerve stimulation may be conducted in an outpatient clinical setting using temporary wire leads. Due to the incidence of lead migration, a 2-step process in a surgical setting is recommended. In the initial test phase, wire leads are inserted under the skin and if 50% improvement is reported, the patient may elect permanent implantation with a pacemaker-like stimulator. If the test phase is unsuccessful, the leads are then removed.

Outcomes

The general outcomes of interest are reduced symptoms and improved quality of life. Outcomes are measured following the 12-week treatment regimen.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;

- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded

Review of Evidence

Systematic Reviews

Amundsen et al (2024) conducted a systematic review and meta-analysis to indirectly compare the efficacy and safety of sacral neuromodulation (SNM) and implantable tibial neuromodulation (iTNM) for the treatment of OAB. Of the 20 studies included in the analysis, 3 were RCTs and the others were a prospective interventional, prospective observational, or retrospective studies. A total of 1766 patients treated with either SNM (n=1416) or iTNM (n=350) were included. The primary outcomes were the percentage of patients with a ≥ 50% reduction in urgency urinary incontinence (UUI) episodes, urinary frequency, and/or OAB symptoms. Primary safety measures included the rate of device-related adverse events. The primary results showed that the UUI responder rate was similar for both SNM and iTNM, with weighted averages of 71.8% and 71.3%, respectively. Similarly, weighted averages of OAB responder rates were 73.9% for SNM and 79.4% for iTNM. The rate of device-related AEs was 12.7% for SNM and 9.6% for iTNM. The authors concluded that both SNM and iTNM have similar efficacy and safety for the treatment of OAB and UUI, including significant improvements in quality of life and low rates of procedure and device-related adverse events. Noted limitations included differences in study populations, geography, study methods, efficacy definitions, and stage of device development. Additionally, the length of follow-up data available for iTNM was shorter than for SNM, and none of the studies identified were direct comparisons of the two interventions.

Nonrandomized Studies

Rogers et al (2021) evaluated the safety and efficacy of the wireless eCoin device in a single-arm, open-label trial at 15 sites in the US. A total of 132 patients with refractory (failed ≥1 second or third-line therapy) OAB received the eCoin device and were included in the intention-to-treat analysis. The majority of patients were female (98%) and 26% had received prior PTNS therapy. At 24-week follow-up, 69% (CI, 61% to 77%) of patients had a 50% reduction in urge urinary incontinence symptoms based on 3-day voiding diaries and were considered "responders". Results were similar at weeks 36 and 48 with 70% (CI, 62% to 78%) and 68% (CI, 60% to 76%) of patients responding, respectively. Fewer patients reported 100% reduction in symptoms with only 21% of patients reporting 100% response at 48 weeks. By 48 weeks there was a mean decrease in urge urinary incontinence episodes (-2.61), urinary voids (-2.12), urgency episodes (-1.49), and nocturia episodes (-0.51). Outcomes were not stratified by prior treatments received. Outcomes were impacted by the COVID-19 pandemic. Pre-pandemic and in-person responder rates were 75% and 74%, respectively, whereas the responder rate during the pandemic was 60% (n=25) and the responder rate of remote visits was 57% (n=14). Adverse events related to the device or procedure were reported in 20% of patients and most were mild (11%) to moderate (6%). There were 3 severe adverse events, including 1 post-operative wound infection, 1 implant site infection, and 1 device stimulation issue. While the study met its primary performance goal of at least a 40% response rate after 48 weeks of therapy, the certainty of this data is limited by the lack of blinding and a control group and the fact that a performance goal was identified after patients had already been implanted. Thus, the FDA has required the manufacturer of the eCoin system to conduct a post-approval study to provide greater certainty of the potential benefit of the device. It is also intended to address safety concerns regarding device explantation and reimplantation following battery depletion given that the study observed the need

to re-implant the device after only 1 year. Possible reasons for the negative impact of COVID-19 on the 48-week response rate were not explored.

A feasibility study conducted by MacDiarmid et al (2019) for the eCoin device conducted in the US and New Zealand initially enrolled 46 patients at 7 sites and found reduced urge urinary incontinence episodes at 3 months follow-up (from 4.2 to 1.7 daily episodes; p=.001). Subsequent long-term data published in 2021 indicate continued safety and efficacy of eCoin with 65% of patients considered responders and 26% of responders having complete continence at 12 months and only 1 serious infection-related adverse event. A follow-up study of 23 patients who were reimplanted with an eCoin device after 1 year with a second-generation device found reimplantation to be successful with 74% and 82% of patients having at least 50% reduction in episodes of urge urinary incontinence at 12 and 24 weeks, respectively. No serious device-related adverse events were reported.

Section Summary: Implantable Tibial Nerve Stimulation for Non-Neurogenic Urinary Dysfunction Including Overactive Bladder

No RCTs were identified that evaluated implantable PTNS for treating non-neurogenic urinary dysfunction including overactive bladder. An open-label, single-arm study evaluating the first FDA-approved wireless implantable posterior tibial nerve stimulation device (eCoin) demonstrated a 68% response rate at 48 weeks of follow-up. However, the certainty of the evidence is limited by the lack of comparator group and a lower response rate during the COVID-19 pandemic. An ongoing post-approval study may elucidate the certainty of benefit, including safety of reimplantation given battery lifespan concerns.

Neurogenic Bladder Dysfunction

Clinical Context and Therapy Purpose

The purpose of percutaneous PTNS in individuals who have neurogenic bladder dysfunction is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with neurogenic bladder dysfunction. Symptoms may include urinating small amounts often, problems starting urination, problems emptying the bladder, inability to detect a full bladder, and losing bladder control.

Interventions

The therapy being considered is percutaneous PTNS. During percutaneous PTNS, a needle is inserted above the medial malleolus into the posterior tibial nerve followed by the application of low-voltage (10 mA, 1-10 Hz frequency) electrical stimulation. Noninvasive PTNS may be 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.

Comparators

The following therapies are currently being used to make decisions about neurogenic bladder dysfunction: conservative treatments (e.g., medication to relax the bladder or to activate pelvic muscles, catheterization to empty the bladder, pelvic floor muscle training), botulinum toxin, and SNS.

Botulinum toxin is injected into the detrusor muscle. However, the toxin increases the risk of urinary retention and is not recommended for patients with a history of urinary retention or recurrent UTIs.

Sacral nerve stimulation may be conducted in an outpatient clinical setting using temporary wire leads. Due to the incidences of lead migration, a 2-step process in a surgical setting is recommended. In the initial test phase, wire leads are inserted under the skin and if 50% improvement is reported, the patient may elect permanent implantation with a pacemaker-like stimulator. If the test phase is unsuccessful, the leads are then removed.

Outcomes

The general outcomes of interest are reduced symptoms and improved quality of life. Outcomes are measured following the 12-week treatment regimen.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

In April of 2019 Hayes completed a Health Technology Assessment (HTA) which was last reviewed in April of 2022 on percutaneous tibial nerve stimulation for the treatment of symptomatic neurogenic lower urinary tract dysfunction. One randomized controlled trial (RCT) [Eftekhar et al (2014)] and 7 pretest/posttest clinical studies (Kabay et al., 2009; Gobbi et al., 2011; El-Senousy et al., 2013; Zecca et al., 2014; Kabay et al., 2016; Kabay et al., 2017; Tudor et al., 2018) met the inclusion criteria. Although authors concluded that PTNS may provide subjective and objective improvement over the short term, they rated the body of the evidence as of very low quality overall. Hayes gave the use of percutaneous tibial nerve stimulation (PTNS) for treatment of neurogenic lower urinary tract dysfunction in adult patients with symptoms that persist or have not responded to alternative therapies who have no contraindications to this procedure a D^2 rating. According to Hayes a D^2 rating indicates, “insufficient evidence. There is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management."

Schneider et al (2015) published a systematic review on tibial nerve stimulation (transcutaneous and percutaneous) for treating neurogenic lower urinary tract dysfunction. In a literature search through January 2015, 16 studies were identified: 4 RCTs, 9 prospective cohort studies, 2 retrospective case series, and 1 case report. Sample sizes of the included studies were small; most included fewer than 50 patients, and none had a sample size larger than 100 patients. Three of the 4 RCTs used TTNS, and the fourth study, which was conducted in Iran, stated that PTNS was used but did not specify the device. The 4 RCTs included different study populations: women with neurogenic bladder (n=1), men with neurogenic OAB (n=1), multiple sclerosis patients (n=1), and Parkinson disease patients (n=1). Comparison interventions were tolterodine, pelvic floor muscle training, lower limb stretching, and sham (1 study each). Pooled analyses were not conducted, and the systematic review mainly discussed intermediate outcomes (e.g., maximum cystometric capacity, maximum detrusor pressure). None of the RCTs reported statistically significant between-group differences in clinical outcome variables (e.g., number of episodes of urgency, frequency, nocturia).

Randomized Controlled Trials

Additional RCTs on TTNS have been published and are discussed below.

Zonic-Imamovic et al (2019) published the results of an RCT evaluating treatment with oxybutynin compared to TTNS in multiple sclerosis patients with OAB. Patients were allocated to 2 groups of 30 patients each. Patients treated with anticholinergic therapy received 5 mg oxybutynin twice daily for 3 months. Patients treated with TTNS were treated at home daily for 30 minutes for 3 months. The OAB-q SF was utilized to assess the frequency of OAB symptoms and the quality of life of patients. For those treated with oxybutynin, the mean symptom subscale score improved from 61.9±6.0 to 32.4±14.8 ($p<.001$), and the mean quality of life subscale score improved from 27.8±13.7 to 56.1±17.3 ($p<.001$) after treatment. For those treated with TTNS, the mean symptom subscale score improved from 61.2±14.6 to 50.8±12.3 ($p=.004$) and the mean quality of life subscale score improved from 28.5±12.6 to 38.3±11.4 ($p=.003$). Final differences in symptoms and quality of life were found to be statistically significant between groups ($p<.001$) and favored treatment with oxybutynin.

A sham-controlled, double-blind RCT of TTNS in patients with neurogenic OAB and women with non-neurogenic OAB was conducted by Welk et al (2020) from January 2016 to March 2019. Fifty patients were recruited (OAB=20; neurogenic=30) and 24 were allocated to the sham group while 26 were allocated to active TTNS therapy. Baseline group characteristics were not specified but were noted to be similar. The majority of neurogenic OAB study participants had multiple sclerosis (22/30; 73%). The primary outcome measure was an improvement of patient perception of bladder condition (PPBC). Active responders did not significantly differ between groups, numbering 3/24 (13%) in the sham group and 4/26 (15%) in the active group ($p=.77$). No significant differences in secondary outcome measures (24-hour pad weight, voiding diary parameters, condition-specific patient-reported outcomes) were noted. The end-of-study marginal mean PPBC score was 3.3 (95% CI, 2.8 to 3.7) versus 2.9 (95% CI, 2.5 to 3.4) in the sham versus active groups, respectively. Findings were not stratified according to neurogenic or non-neurogenic disease. The authors concluded that TTNS does not appear to be effective for treating symptoms in individuals with neurogenic or non-neurogenic OAB.

Sham-controlled trials of TTNS in individuals with acute spinal cord injury (TASCI; NCT03965299) and Parkinson disease (UROPARKTENS; NCT02190851) are ongoing.

Section Summary: Neurogenic Bladder Dysfunction

Few RCTs evaluating percutaneous PTNS for treating neurogenic bladder have been published to date, and all but 1 performed transcutaneous stimulation rather than percutaneous PTNS. Studies varied widely in study populations and comparator interventions. Study findings have not suggested that tibial nerve stimulation significantly reduces incontinence symptoms and improves other outcomes.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2018 Input

Clinical input was sought to help determine whether the use of maintenance posterior tibial nerve stimulation (PTNS) for individuals with non-neurogenic urinary dysfunction including overactive bladder who have failed behavioral and pharmacologic therapy and respond to an initial course of PTNS would provide a clinically meaningful improvement in the net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 3 physician respondents identified by specialty societies.

For individuals with non-neurogenic urinary dysfunction including overactive bladder who have failed behavioral and pharmacologic therapy and respond to an initial course of PTNS, clinical input supports this use provides a clinically meaningful improvement in net health outcome and indicates this use is consistent with generally accepted medical practice.

Further details from clinical input are included in the Appendix.

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 (AUA) and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) 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. In 2024, the AUA/SUFU published a guideline on the diagnosis and treatment of idiopathic overactive bladder. In the unabridged version of the guideline, PTNS is mentioned as a minimally invasive therapy option. The guideline states that “Clinicians may offer minimally invasive procedures to patients who are unable or unwilling to undergo behavioral, non-invasive, or pharmacologic therapies (Clinical Principle)" and " Clinicians may offer patients with OAB, in the context of shared decision making, minimally invasive therapies without requiring trials of behavioral, non-invasive, or pharmacologic management (Expert Opinion)".

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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

REFERENCES

1. Wang M, Jian Z, Ma Y, et al. Percutaneous tibial nerve stimulation for overactive bladder syndrome: a systematic review and meta-analysis. Int Urogynecol J. Dec 2020; 31(12): 2457-2471. PMID 32681345

2. Xiong SC, Peng L, Hu X, et al. Effectiveness and safety of tibial nerve stimulation versus anticholinergic drugs for the treatment of overactive bladder syndrome: a meta-analysis. Ann Palliat Med. Jun 2021; 10(6): 6287-6296. PMID 34118839

3. Coolen RL, Groen J, Scheepe JR, et al. Transcutaneous Electrical Nerve Stimulation and Percutaneous Tibial Nerve Stimulation to Treat Idiopathic Nonobstructive Urinary Retention: A Systematic Review. Eur Urol Focus. Sep 2021; 7(5): 1184-1194. PMID 33268327

4. Ho FCS, He C, Yao HH, et al. Efficacy of sacral neuromodulation and percutaneous tibial nerve stimulation in the treatment of chronic nonobstructive urinary retention: A systematic review. Neurourol Urodyn. Jun 2021; 40(5): 1078-1088. PMID 33973670

5. Tutolo M, Ammirati E, Heesakkers J, et al. Efficacy and Safety of Sacral and Percutaneous Tibial Neuromodulation in Non-neurogenic Lower Urinary Tract Dysfunction and Chronic Pelvic Pain: A Systematic Review of the Literature. Eur Urol. Mar 2018; 73(3): 406-418. PMID 29336927

6. Tutolo M, Ammirati E, Van der Aa F. What Is New in Neuromodulation for Overactive Bladder?. Eur Urol Focus. Jan 2018; 4(1): 49-53. PMID 29773501

7. Stewart F, Gameiro LF, El Dib R, et al. Electrical stimulation with non-implanted electrodes for overactive bladder in adults. Cochrane Database Syst Rev. Dec 09 2016; 12: CD010098. PMID 27935011

8. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Percutaneous tibial nerve stimulation for the treatment of voiding dysfunction. TEC Assessments. 2013;Volume 28:Tab 10. PMID

9. Burton C, Sajja A, Latthe PM. Effectiveness of percutaneous posterior tibial nerve stimulation for overactive bladder: a systematic review and meta-analysis. Neurourol Urodyn. Nov 2012; 31(8): 1206-16. PMID 22581511

10. Levin PJ, Wu JM, Kawasaki A, et al. The efficacy of posterior tibial nerve stimulation for the treatment of overactive bladder in women: a systematic review. Int Urogynecol J. Nov 2012; 23(11): 1591-7. PMID 22411208

11. Moossdorff-Steinhauser HF, Berghmans B. Effects of percutaneous tibial nerve stimulation on adult patients with overactive bladder syndrome: a systematic review. Neurourol Urodyn. Mar 2013; 32(3): 206-14. PMID 22907807

12. Gaziev G, Topazio L, Iacovelli V, et al. Percutaneous Tibial Nerve Stimulation (PTNS) efficacy in the treatment of lower urinary tract dysfunctions: a systematic review. BMC Urol. Nov 25 2013; 13: 61. PMID 24274173

13. Shamliyan T, Wyman J, Kane RL. Nonsurgical Treatments for Urinary Incontinence in Adult Women: Diagnosis and Comparative Effectiveness (Comparative Effectiveness Review No. 36). Rockville, MD: Agency for Healthcare Research and Quality; 2012.

14. Finazzi-Agro E, Petta F, Sciobica F, et al. Percutaneous tibial nerve stimulation effects on detrusor overactivity incontinence are not due to a placebo effect: a randomized, double-blind, placebo controlled trial. J Urol. Nov 2010; 184(5): 2001-6. PMID 20850833

15. Peters KM, Carrico DJ, Perez-Marrero RA, et al. Randomized trial of percutaneous tibial nerve stimulation versus Sham efficacy in the treatment of overactive bladder syndrome: results from the SUmiT trial. J Urol. Apr 2010; 183(4): 1438-43. PMID 20171677

16. Peters K, Carrico D, Burks F. Validation of a sham for percutaneous tibial nerve stimulation (PTNS). Neurourol Urodyn. 2009; 28(1): 58-61. PMID 18671297

17. Peters KM, Carrico DJ, Wooldridge LS, et al. Percutaneous tibial nerve stimulation for the long-term treatment of overactive bladder: 3-year results of the STEP study. J Urol. Jun 2013; 189(6): 2194-201. PMID 23219541

18. Vecchioli-Scaldazza C, Morosetti C. Effectiveness and durability of solifenacin versus percutaneous tibial nerve stimulation versus their combination for the treatment of women with overactive bladder syndrome: a randomized controlled study with a follow-up of ten months. Int Braz J Urol. Jan-Feb 2018; 44(1): 102-108. PMID 29064651

19. Boudaoud N, Binet A, Line A, et al. Management of refractory overactive bladder in children by transcutaneous posterior tibial nerve stimulation: A controlled study. J Pediatr Urol. Jun 2015; 11(3): 138.e1-10. PMID 25979217

20. Gungor Ugurlucan F, Onal M, Aslan E, et al. Comparison of the effects of electrical stimulation and posterior tibial nerve stimulation in the treatment of overactive bladder syndrome. Gynecol Obstet Invest. 2013; 75(1): 46-52. PMID 23171636

21. Preyer O, Umek W, Laml T, et al. Percutaneous tibial nerve stimulation versus tolterodine for overactive bladder in women: a randomised controlled trial. Eur J Obstet Gynecol Reprod Biol. Aug 2015; 191: 51-6. PMID 26073262

22. Vecchioli-Scaldazza C, Morosetti C, Berouz A, et al. Solifenacin succinate versus percutaneous tibial nerve stimulation in women with overactive bladder syndrome: results of a randomized controlled crossover study. Gynecol Obstet Invest. 2013; 75(4): 230-4. PMID 23548260

23. Schreiner L, dos Santos TG, Knorst MR, et al. Randomized trial of transcutaneous tibial nerve stimulation to treat urge urinary incontinence in older women. Int Urogynecol J. Sep 2010; 21(9): 1065-70. PMID 20458465

24. Peters KM, Macdiarmid SA, Wooldridge LS, et al. Randomized trial of percutaneous tibial nerve stimulation versus extended-release tolterodine: results from the overactive bladder innovative therapy trial. J Urol. Sep 2009; 182(3): 1055-61. PMID 19616802

25. MacDiarmid SA, Peters KM, Shobeiri SA, et al. Long-term durability of percutaneous tibial nerve stimulation for the treatment of overactive bladder. J Urol. Jan 2010; 183(1): 234-40. PMID 19913821

26. Rogers A, Bragg S, Ferrante K, et al. Pivotal Study of Leadless Tibial Nerve Stimulation with eCoin® for Urgency Urinary Incontinence: An Open-Label, Single Arm Trial. J Urol. Aug 2021; 206(2): 399-408. PMID 33797291

27. U.S. Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): eCoin Peripheral Neurostimulator System (P200036). March 1, 2022; https://www.accessdata.fda.gov/cdrh_docs/pdf20/P200036B.pdf. Accessed August 19, 2025

28. MacDiarmid S, Staskin DR, Lucente V, et al. Feasibility of a Fully Implanted, Nickel Sized and Shaped Tibial Nerve Stimulator for the Treatment of Overactive Bladder Syndrome with Urgency Urinary Incontinence. J Urol. May 2019; 201(5): 967-972. PMID 31009968

29. Gilling P, Meffan P, Kaaki B, et al. Twelve-month Durability of a Fully-implanted, Nickel-sized and Shaped Tibial Nerve Stimulator for the Treatment of Overactive Bladder Syndrome with Urgency Urinary Incontinence: A Single-Arm, Prospective Study. Urology. Nov 2021; 157: 71-78. PMID 34048826

30. Kaaki B, English S, Gilling P, et al. Six-Month Outcomes of Reimplantation of a Coin-Sized Tibial Nerve Stimulator for the Treatment of Overactive Bladder Syndrome With Urgency Urinary Incontinence. Female Pelvic Med Reconstr Surg. May 01 2022; 28(5): 287-292. PMID 35536667

31. Schneider MP, Gross T, Bachmann LM, et al. Tibial Nerve Stimulation for Treating Neurogenic Lower Urinary Tract Dysfunction: A Systematic Review. Eur Urol. Nov 2015; 68(5): 859-67. PMID 26194043

32. Monteiro ES, de Carvalho LB, Fukujima MM, et al. Electrical stimulation of the posterior tibialis nerve improves symptoms of poststroke neurogenic overactive bladder in men: a randomized controlled trial. Urology. Sep 2014; 84(3): 509-14. PMID 25168524

33. Perissinotto MC, D'Ancona CA, Lucio A, et al. Transcutaneous tibial nerve stimulation in the treatment of lower urinary tract symptoms and its impact on health-related quality of life in patients with Parkinson disease: a randomized controlled trial. J Wound Ostomy Continence Nurs. Jan-Feb 2015; 42(1): 94-9. PMID 25549314

34. Gaspard L, Tombal B, Opsomer RJ, et al. [Physiotherapy and neurogenic lower urinary tract dysfunction in multiple sclerosis patients: a randomized controlled trial]. Prog Urol. Sep 2014; 24(11): 697-707. PMID 25214451

35. Eftekhar T, Teimoory N, Miri E, et al. Posterior tibial nerve stimulation for treating neurologic bladder in women: a randomized clinical trial. Acta Med Iran. 2014; 52(11): 816-21. PMID 25415813

36. Zonić-Imamović M, Imamović S, Čičkušić A, et al. Effects of Treating an Overactive Urinary Bladder in Patients with Multiple Sclerosis. Acta Med Acad. Dec 2019; 48(3): 271-277. PMID 32124625

37. Welk B, McKibbon M. A randomized, controlled trial of transcutaneous tibial nerve stimulation to treat overactive bladder and neurogenic bladder patients. Can Urol Assoc J. Jul 2020; 14(7): E297-E303. PMID 32017693

38. Zecca C, Digesu GA, Robshaw P, et al. Maintenance percutaneous posterior nerve stimulation for refractory lower urinary tract symptoms in patients with multiple sclerosis: an open label, multicenter, prospective study. *J Urol.* 2014;191(3):697-702.

39. Zecca C, Panicari L, Disanto G, et al. Posterior tibial nerve stimulation in the management of lower urinary tract symptoms in patients with multiple sclerosis. *Int Urogynecol J.* 2016;27(4):521-527.

40. Eftekhar T, Teimoory N, Miri E, et al. Posterior tibial nerve stimulation for treating neurologic bladder in women: a randomized clinical trial. *Acta Med Iran.* 2014;52(11):816-821.

41. El-Senousy MY, Mohammed ES, Fayed HA. Efficacy of posterior tibial nerve stimulation on detrusor overactivity of idiopathic parkinson's disease patients clinical and urodynamic evaluation. *Egypt J Neurol Psychiat Neurosurg.* 2013;50(03):265-270.

42. Kabay S, Canbaz Kabay S, Cetiner M, et al. The clinical and urodynamic results of percutaneous posterior tibial nerve stimulation on neurogenic detrusor overactivity in patients with Parkinson's disease. *Urology.* 2016;87:76-81.

43. Kabay S, Kabay SC, Yucel M, et al. The clinical and urodynamic results of a 3-month percutaneous posterior tibial nerve stimulation treatment in patients with multiple sclerosis-related neurogenic bladder dysfunction. *Neurourol Urodyn.* 2009;28(8):964-968.

44. Kabay SC, Kabay S, Mestan E, et al. Long term sustained therapeutic effects of percutaneous posterior tibial nerve stimulation treatment of neurogenic overactive bladder in multiple sclerosis patients: 12-months results. *Neurourol Urodyn.* 2017;36(1):104-110.

45. Gobbi C, Digesu GA, Khullar V, et al. Percutaneous posterior tibial nerve stimulation as an effective treatment of refractory lower urinary tract symptoms in patients with multiple sclerosis: preliminary data from a multicentre, prospective, open label trial. *Mult Scler.* 2011;17(12):1514-1519.

46. Tudor KI, Sakakibara R, Panicker JN. Neurogenic lower urinary tract dysfunction: evaluation and management. *J Neurol.* 2016;263(12):2555-2564.

47. Lightner DJ, Gomelsky A, Souter L, et al. Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults: AUA/SUFU Guideline Amendment 2019. J Urol. Sep 2019; 202(3): 558-563. PMID 31039103

48. Cameron AP, Chung DE, Dielubanza EJ, et al. The AUA/SUFU guideline on the diagnosis and treatment of idiopathic overactive bladder. J Urol. Published online April 23, 2024. doi:10.1097/JU.0000000000003985. https://www.auajournals.org/doi/10.1097/JU.0000000000003985 Accessed August 19, 2025

49. U.S. Food & Drug Administration. FDA New Release. RFA Roundup: August 18, 2023. Available at: https://www.fda.gov/news-events/press-announcements/fda-roundup-august-18-2023. Accessed August 19, 2025.

50. ACOG Practice Bulletin No. 155: Urinary Incontinence in Women. Obstet Gynecol. Nov 2015; 126(5): e66-e81. PMID 26488524

51. Hayes, a symplr company. Health Technology Assessment. Percutaneous Tibial Nerve Stimulation for the Treatment of Symptomatic Neurogenic Lower Urinary Tract Dysfunction. Hayes, Inc. April 15, 2019. Annual Review April 1, 2022. Available at: www.hayesinc.com. Accessed August 19, 2025.

52. Hayes, a symplr company. Health Technology Assessment. Comparative Effectiveness Review of Percutaneous Tibial Nerve Stimulation for the Treatment of Symptomatic Non-Neurogenic Overactive Bladder. Hayes. Inc. October 31, 2018. Annual Review: November 15, 2022. Available at: www.hayesinc.com. Accessed August 19, 2025.

53. Xavier K, Miller D, Benson K, et al. Feasibility Study to Characterize the Implant Procedure for a Leadless Tibial Nerve Stimulator. *Neurourology and Urodynamics.* 2023;42(S1):S216-S217. http://dx.doi.org/10.1002/nau.25154

54. Lee UJ, Xavier K, Benson K, et al. Rationale and design of an implant procedure and pivotal study to evaluate safety and effectiveness of Medtronic's tibial neuromodulation device. *Contemp Clin Trials Commun.* 2023;35:101198. http://dx.doi.org/10.1016/j.conctc.2023.101198

55. Kobashi K, Nitti V, Margolis E, et al. A Prospective Study to Evaluate Efficacy Using the Nuro Percutaneous Tibial Neuromodulation System in Drug-Naive Patients With Overactive Bladder Syndrome. *Urology.* 2019;131:77-82. http://dx.doi.org/10.1016/j.urology.2019.06.002

CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	0816T	Implantation of integrated neurostimulation system for bladder dysfunction including electrode(s) (e.g., array or leadless), and pulse generator or receiver
	64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming
	64999	Unlisted procedure, nervous system *(when specified for eCoin)*
	0587T	Percutaneous implantation or replacement of integrated single device neurostimulation system for bladder dysfunction including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve
	0588T	Revision or removal of percutaneously placed integrated single device neurostimulation system for bladder dysfunction 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 for bladder dysfunction (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	Electronic analysis with complex programming of implanted integrated neurostimulation system for bladder dysfunction (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
	0816T	Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrodes(s) (e.g., array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subcutaneous (*may be utilized for eCoin and Altaviva*)

	0817T	Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrodes(s) (e.g., array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subfascial (*may be utilized for eCoin*)
	0818T	Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subcutaneous (*may be utilized for eCoin*)
	0819T	Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subfascial (*may be utilized for eCoin*)
HCPCS		
	L8679	Implantable neurostimulator, pulse generator; any type
	C1787	Patient Programmer, Neurostimulator
	C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
Type of Service	Surgery	
Place of Service	Inpatient/Outpatient	

POLICY HISTORY

Date	Reason	Action
September 2025	Annual Review	Policy Renewal
September 2024	Annual Review	Policy Revised
August 2023	Annual Review	Policy Revised
July 2022	Interim Review	Policy Revised
June 2022	Annual Review	Policy Revised
April 2022	Interim Review	Policy Revised
June 2021	Annual Review	Policy Revised

June 2020	Annual Review	Policy Revised
June 2019	Annual Review	Policy Revised
June 2018	Annual Review	Policy Revised
June 2017	Annual Review	Policy Revised
July 2016	Annual Review	Policy Revised
July 2015	Annual Review	Policy Revised
August 2014	Annual Review	Policy Renewed
May 2014	Interim Review	Policy Revised
September 2013	Annual Review	Policy Revised
October 2012	Annual Review	Policy Renewed
October 2011	Annual Review	Policy Renewed
September 2010	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

*CPT® is a registered trademark of the American Medical Association.

APPENDIX

Appendix 1:

Clinical Input – Summary

2018 Input

Clinical input was sought to help determine whether the use of maintenance PTNS for individuals with non-neurogenic urinary dysfunction including overactive bladder who have failed behavioral and pharmacologic therapy and respond to an initial course of PTNS would provide a clinically meaningful improvement in the net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 3 physician respondents identified by specialty societies.

For individuals with non-neurogenic urinary dysfunction including overactive bladder who have failed behavioral and pharmacologic therapy and respond to an initial course of PTNS, clinical input supports this use provides a clinically meaningful improvement in net health outcome and indicates this use is consistent with generally accepted medical practice.

Clinical Input – Respondents

Clinical input was provided by the following physician members identified by a specialty society:

- David A. Ginsberg*, MD, Urology, Female pelvic medicine & reconstructive surgery, identified by the American Urological Association (AUA)
- Howard B. Goldman*, MD, Urology, identified by the American Urological Association (AUA)
- Matthew P. Rutman, MD, Urology, Female pelvic medicine & reconstructive surgery, identified by the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU)

* Indicates that conflicts of interest related to the topic where clinical input is being sought were identified by this respondent (see Clinical Input – Detailed Responses).

Clinical input provided by the specialty society at an aggregate level is attributed to the specialty society. Clinical input provided by a physician member designated by the specialty society or health system is attributed to the individual physician and is not a statement from the specialty society or health system. Specialty society and physician respondents participating in the Evidence Street® clinical input process provide a review, input, and feedback on topics being evaluated by Evidence Street. However, participation in the clinical input process by a special society and/or physician member designated by the specialty society or health system does not imply an endorsement or explicit agreement with the Evidence Opinion published by BCBSA or any Blue Plan.

Individual physician respondents answered at the individual level. Specialty Society respondents provided aggregate information that may be relevant to the group of clinicians who provided input to the Society-level response.

Clinical Input – Objective

Percutaneous tibial nerve stimulation (PTNS) (also known as posterior tibial nerve stimulation) is a technique of electrical neuromodulation used primarily for treating voiding dysfunction.

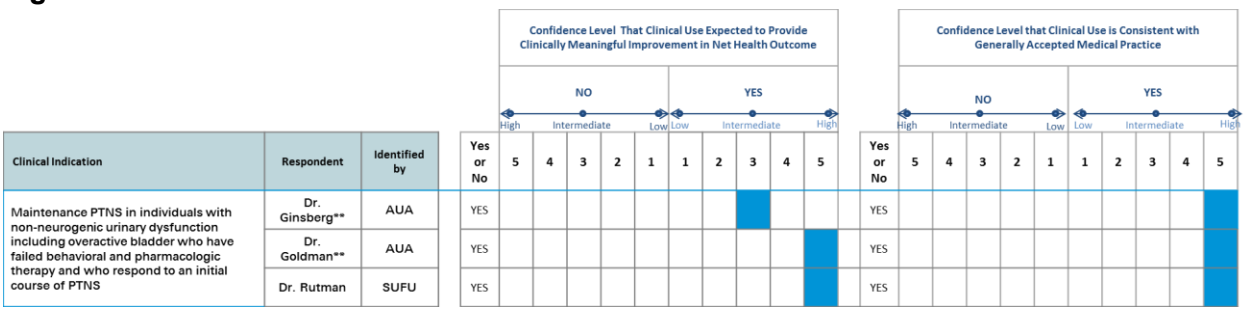
The following PICO formulation is of interest for this request.

Populations	Interventions	Comparators	Outcomes
Individuals: • With non-neurogenic urinary dysfunction including overactive bladder who have failed behavioral and pharmacologic therapy who respond to an initial course of percutaneous tibial nerve stimulation	**Interventions of interest are:** • Maintenance percutaneous tibial nerve stimulation	**Comparators of interest are:** • Sacral nerve stimulation • Botulinum toxin	**Relevant outcomes include:** • Symptoms • Change in disease status • Functional outcomes • Quality of life • Treatment-related morbidity

Clinical input is sought to help determine whether the use of a particular technology for a population would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice.

Clinical Input– Responses

Figure 1.



Clinical Indication	Respondent	Identified by	Yes or No	5	4	3	2	1	1	2	3	4	5	Yes or No	5	4	3	2	1	1	2	3	4	5
Maintenance PTNS in individuals with non-neurogenic urinary dysfunction including overactive bladder who have failed behavioral and pharmacologic therapy and who respond to an initial course of PTNS	Dr. Ginsberg**	AUA	YES								■			YES										■
	Dr. Goldman**	AUA	YES										■	YES										■
	Dr. Rutman	SUFU	YES										■	YES										■

** Indicates that conflicts of interest related to the topic where clinical input is being sought were identified by this respondent.

Clinical Input– Detailed Responses

Appendix Table 1. Respondent Profile

	Physician				
No.	**Name**	**Degree**	**Institutional Affiliation**	**Clinical Specialty**	**Board Certification and Fellowship Training**
Identified by American Urological Association (AUA)					
1	David A. Ginsberg	MD	University of Southern California	Urology, Female pelvic medicine & reconstructive surgery	Urology, Female pelvic medicine & reconstructive surgery
2	Howard B. Goldman	MD	Cleveland Clinic	Urology	Urology, Female pelvic medicine & reconstructive surgery
Identified by Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU)					
3	Matthew P. Rutman	MD	Columbia University	Urology	Female pelvic medicine & reconstructive surgery

Appendix Table 2. Respondent Conflict of Interest Disclosure

No.	1. Research support related to the topic where clinical input is being sought		2. Positions, paid or unpaid, related to the topic where clinical input is being sought		3.Reportable, more than $1000,health care-related assets or sources of income for myself, my spouse, or my dependent children related to the topic where clinical input is being sought		4. Reportable, more than $350, gifts or travel reimbursements for myself, my spouse, or my dependent children related to the topic where clinical input is being sought	
	Yes/No	**Explanation**	**Yes/No**	**Explanation**	**Yes/No**	**Explanation**	**Yes/No**	**Explanation**
1	Yes	We are a study site for Bioness - no patients recruited yet	No		No		No	
2	No		Yes	I am on medical advisory board of Cogentix which is company that sells one of the PTNS devices	No		No	
3	No		No		No		No	

Individual physician respondents answered at the individual level. Specialty Society respondents provided aggregate information that may be relevant to the group of clinicians who provided input to the Society-level response.

1. Based on the evidence and your clinical experience for the use of maintenance PTNS in individuals with non-neurogenic urinary dysfunction including overactive bladder who have failed behavioral and pharmacologic therapy and who respond to an initial course of PTNS, please describe the narrative rationale that includes: (1) relevant authoritative scientific evidence and/or relevant clinical scenarios (e.g., a chain of evidence) supporting that use of the technology provides clinical meaningful improvement in net health outcome; and (2) any relevant patient inclusion/exclusion criteria or clinical context important to achieve a clinically meaningful improvement in net health outcome. Please include the PMID for any relevant references.
    - In particular, please also outline the management criteria, including frequency and duration, for maintenance PTNS treatments to achieve a clinically meaningful improvement in net health outcome.

No.	Rationale
1	I am not sure there is much to add. This review has looked at the relevant studies. I am not aware of medical inclusion/exclusion criteria that help define the optimal patient for this technology. At one point I assumed it would not work on patients with peripheral neuropathy; however, we do have a few patients in our practice that this has helped. The one "exclusion" criteria that we do often see is not medical but geographical - patients that live far away do not want to come to our office weekly for the first 3 months of the treatment. In regards to duration we maintain patients on a monthly treatment. We do not give them leeway in regard to symptoms such that they might be stimulated more often.
2	At this time there is ample evidence to recommend the use of PTNS in non-neurogenic patients with refractory OAB. It is offered as an alternative to Botox and sacral neuromodulation understanding that while the outcomes of PTNS are not as robust as the others, it is essentially without any significant risk to the patient. Patients typically have it done once a week for 12 weeks and then, if successful, every 4-6 weeks after that. They are seen in office by MD on a yearly basis to ensure efficacy is continuing.
3	The available literature supports the use of PTNS in patients with non-neurogenic (idiopathic) OAB. There is good data to show it has improvement versus antimuscarinic therapy (Orbit Trial) as well as a sham procedure. There is essentially no risk to the procedure and it is very well tolerated. In my practice, patients respond well and seem to enjoy the ability to be an active participant in treatment for OAB. It is certainly better tolerated and has better compliance than antimuscarinic therapy. Management criteria would be once a week for 12 weeks and monthly afterward for maintenance.

2. Based on the evidence and your clinical experience for each of the clinical indications described in Question 1a and 1b:
    a. Respond YES or NO for each clinical indication whether the intervention would be expected to provide a clinically meaningful improvement in net health outcome; AND
    b. Rate your level of confidence in your YES or NO response using the 1 to 5 scale outlined below.

No.	Indications	Yes/No	Low Confidence		Intermediate Confidence		High Confidence
			1	2	3	4	5
1	Maintenance PTNS in individuals with non-neurogenic urinary dysfunction including overactive bladder who have failed behavioral and pharmacologic therapy and who respond to an initial course of PTNS	Yes			X		
2	Maintenance PTNS in individuals with non-neurogenic urinary dysfunction including overactive bladder who have failed behavioral and pharmacologic therapy and who respond to an initial course of PTNS	Yes					X
3	Maintenance PTNS in individuals with non-neurogenic urinary dysfunction including overactive bladder who have failed behavioral and pharmacologic therapy and who respond to an initial course of PTNS	Yes					X

3. Based on the evidence and your clinical experience for each of the clinical indications described in Question 1a and 1b:
    a. Respond YES or NO for each clinical indication whether this intervention is consistent with generally accepted medical practice; AND
    b. Rate your level of confidence in your YES or NO response using the 1 to 5 scale outlined below.

No.	Indications	Yes/No	Low Confidence		Intermediate Confidence		High Confidence
			1	2	3	4	5
1	Maintenance PTNS in individuals with non-neurogenic urinary dysfunction including overactive bladder who have failed behavioral and pharmacologic therapy and who respond to an initial course of PTNS	Yes					X
2	Maintenance PTNS in individuals with non-neurogenic urinary	Yes					X

No.	Indications	Yes/No	Low Confidence		Intermediate Confidence		High Confidence
	dysfunction including overactive bladder who have failed behavioral and pharmacologic therapy and who respond to an initial course of PTNS						
3	Maintenance PTNS in individuals with non-neurogenic urinary dysfunction including overactive bladder who have failed behavioral and pharmacologic therapy and who respond to an initial course of PTNS	Yes					X

4. Additional narrative rationale or comments and/or any relevant scientific citations (including the PMID) supporting your clinical input on this topic.

No.	Additional Comments
1	In regard to question #4, there is high confidence that PTNS is part of the generally accepted medical practice. However, please remember that many practitioners do not offer this technique. This is because many urologists and gynecologists do not optimally embrace 3rd tier options for OAB (e.g., SNS, PTNS, onaotA); this is NOT because they do not believe in the technology.
2	None
3	None

5. Is there any evidence missing from the attached draft review of evidence that demonstrates clinically meaningful improvement in net health outcome? If YES, please share any relevant scientific citations of missing evidence (including the PMID).

No.	Yes/No	Citations of Missing Evidence
1	Yes	This is really a maybe more than a yes. There are 2-3 studies evaluating the outcomes of PTNS in MS and Parkinson's pts that suggest nice outcomes. However, none of them are well done RCTs. Most of these studies include the authors Kabay or Zecca.
2	No	
3	No	