7.01.106	Percutaneous Tibial Nerve Stimulation		
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Section:	7.0 Surgery	**Page:**	Page 1 of 27

Policy Statement

Percutaneous tibial nerve stimulation for an initial 12-week course may be considered **medically necessary** for individuals with non-neurogenic urinary dysfunction including overactive bladder when **both** of the following have been met:

- Failed behavioral therapy following an appropriate duration of 8 to 12 weeks without meeting treatment goals
- Failed pharmacologic therapy following 4 to 8 weeks of treatment without meeting treatment goals

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

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

- Neurogenic bladder dysfunction
- Fecal incontinence

Policy Guidelines

Patients may be considered to have failed behavioral therapies following an appropriate duration of 8 to 12 weeks without meeting treatment goals (Gormley et al [2015]).

Patients may be considered to have failed pharmacologic therapies following 4 to 8 weeks of treatment without meeting treatment goals (Gormley et al [2015]).

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

Coding

There is a specific CPT code for this procedure:

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

Description

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

Related Policies

- Biofeedback as a Treatment of Fecal Incontinence or Constipation
- Biofeedback as a Treatment of Urinary Incontinence in Adults
- Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence
- Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence
- Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy
- Sacral Nerve Neuromodulation/Stimulation
- Transanal Radiofrequency Treatment of Fecal Incontinence

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

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 percutaneous tibial nerve stimulators have been cleared for marketing through the 510(k) process. They are listed in Table 1.

The Urgent® PC Neuromodulation System and NURO™ Neuromodulation System are not FDA-cleared for other indications, such as the treatment of fecal incontinence.

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

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

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

FDA: Food and Drug Administration.

Rationale

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, and 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.

PTNS is less invasive than traditional sacral nerve neuromodulation (see Blue Shield of California Medical Policy: Sacral Nerve Neuromodulation/Stimulation), 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.

PTNS has also been proposed as a treatment for non-neurogenic and neurogenic bladder syndromes and fecal incontinence.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a 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 to 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 a technology, 2 domains are examined: the relevance and the quality and credibility. To be

relevant, studies must represent one 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 (RCTs) 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.

Non-Neurogenic Urinary Dysfunction Including Overactive Bladder
Clinical Context and Therapy Purpose
The purpose of percutaneous tibial nerve stimulation (PTNS) in patients who have non-neurogenic urinary dysfunction including overactive bladder (OAB) and have failed behavioral and pharmacologic therapy or 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 question addressed in this evidence review is: Does the use of PTNS improve the net health outcome in patients with non-neurogenic urinary dysfunction including OAB and have failed behavioral and pharmacologic therapy or those with OAB who have responded to an initial course of PTNS?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant populations of interest are:
- Patients who have non-neurogenic urinary dysfunction including OAB who have failed behavioral and pharmacologic therapy and
- Patients with OAB responsive to an initial course of 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 infections.

SNS 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 number of voids per day) and improved quality of life.

Timing
Outcomes are measured following the 12-week treatment regimen.

Setting
PTNS is administered in an outpatient clinical setting.

Sham-Controlled Randomized Trials
The Sham Effectiveness in Treatment of Overactive Bladder Symptoms (SUmiT) trial, reported by Peters et al (2010), was a sham-controlled randomized trial.[1] Before conducting the trial, investigators performed a pilot study in healthy volunteers to determine the adequacy of a sham PTNS intervention.[2] 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 for urgency, self-reported bladder symptoms lasting at least 3 months, and having failed conservative care for these symptoms or a diagnosis of OAB. OAB 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 transcutaneous electrical nerve stimulation surface electrodes were used. The transcutaneous electrical nerve stimulation 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 end point 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 Sustained Therapeutic Effects of Percutaneous Tibial Nerve Stimulation (STEP) trial, an extension of the SUmiT study, included only responders from the PTNS group.[3] 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. PTNS 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, stomach ache, pelvic pain, urinary tract infection, 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 2 and 3 summarize the SUmiT RCT and STEP extension study.

Table 2. 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)[1]; SUmiT	U.S.	23	2008-2009	110/103	110/105	GRA at 13 wk
Peters et al (2013)[3]; 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 3. 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)[1]				
GRA (13 wk)	60/110 (54.5)	23/110 (20.9)	NR	<0.001
STEP (2013)[3]				
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.[4] 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 RCTs

An RCT comparing PTNS with medication for the treatment of OAB was published by Vecchioli-Scaldazza et al (2018).[5] 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 posttreatment. Patients in all 3 arms experienced significant reductions from baseline in daytime frequency, night-time frequency, and urgency. PTNS 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.[4,6-10,5] The trials reported inconsistent findings on short-term efficacy, and only one 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.[8]

There were no significant differences between groups on the reduction of incontinence episodes in 24 hours (p=0.89) or quality of life (p=0.07).

Another RCT comparing PTNS with medication—in this case, oral solifenacin—was a crossover trial published by Vecchioli-Scaldazza et al (2013).[9] 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.[10] 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=0.001).

Gungor Ugurlucan et al (2013) in Turkey compared transvaginal electrical stimulation (n=38) with PTNS (n=21) in women who had OAB.[7] The electrical stimulation protocol consisted of 20-minute treatments, 3 times a week for 6 to 8 weeks. PTNS 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=0.54). 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=0.03). 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 Overactive Bladder Innovative Therapy (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.[11] 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. A total of 100 participants were randomized, with 87 completing the trial. In the PTNS arm, subjects received 12 weekly 30-minute treatments. PTNS parameters were maximized based on patient motor and sensory responses. Subjects on tolterodine received a 90-day prescription for 4 mg daily with a subsequent decrease to 2 mg daily if intolerability was experienced. Voiding diary data were available for 84 participants; 41 (82%) of 50 in the PTNS group and 43 (86%) of 50 in the tolterodine group.

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 (e.g., 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.[12] 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 4 and 5 summarize the OrBIT and OrBIT 1-year follow-up studies.

Table 4. Summary of OrBIT RCT Characteristics

Study	Countries	Sites	Dates	Randomized/Completed		Outcome[a] Reduction in Voids
				PTNS	Tolterodine	
Peters et al (2009)[11]	U.S.	11	2006-2008	50/41	50/43	Reported
MacDiarmid et al (2010)[12] 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 5. Summary of OrBIT RCT Results

Study	Primary Outcome: Mean Reduction in Voids per Day (SD)			
OrBIT (2009)[11]	PTNS (n=41)		Tolterodine (n=43)	
	Baseline	12 Weeks	Baseline	12 Weeks
Voids per day	12.1 (3.1)	-2.4 (4.0)	12.5 (3.7)	-2.5 (3.9)
p		<0.001		<0.001
Confidence interval		NR		NR
OrBIT 1-y follow-up (2010)[12]	PTNS (n=25)			
	Baseline	12 Months		
Voids per day	12.4 (3.5)	-2.8 (3.7)	Not applicable	Not applicable
p		<0.001		
Confidence interval		NR		

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

Systematic Reviews

Tutulo et al (2018) searched the literature through December 2017 and identified 21 studies using either sacral neuromodulation (also called SNS) or PTNS to treat lower urinary tract dysfunction

and chronic pelvic pain not responding to standard therapies.[13] Reviewers concluded that both SNS and PTNS were effective therapies. PTNS 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.[14] 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.[15] 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 (total N=4424 randomized participants). Reviewers included several trials discussed above: the OrBIT (Peters et al [2009]) and OrBIT follow-up (MacDiarmid et al [2010]) trials, SUmiT (Peters et al [2010]) trial, STEP (Peters et al [2013]) trial, 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 6. PTNS results were combined for vaginal and rectal electrical stimulation.

Table 6. 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).[15]
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 Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment (2013) evaluating PTNS as a treatment for voiding dysfunction.[16] 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 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.[17-20] Only one conducted pooled analyses of study results.[17] This review, by Burton et al (2012), conducted a pooled analysis of data from 4 trials (two of which were abstracts) comparing PTNS with sham treatment. Reviewers found a significantly higher risk of successful treatment with PTNS (relative risk, 7.02; 95% confidence interval [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 above) 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.[21] 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; one 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 statistically significant improvement in urinary incontinence in the PTNS group compared with the control group (relative risk, 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).[4] 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.

Section Summary: Non-Neurogenic Urinary Dysfunction Including OAB

Initial Course of Percutaneous Tibial Nerve Stimulation

For individuals who have non-neurogenic urinary dysfunction including OAB who have failed behavioral and pharmacologic therapy and received an initial course of 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 PTNS. The largest, highest quality study was the blinded sham-controlled SUmiT trial. This trial reported a statistically significant benefit of PTNS vs sham at 12 weeks. In another small sham-controlled trial, a 50% reduction in urge incontinent episodes was attained in 71% of the PTNS group compared with 0% in the sham group. The nonblinded OrBIT trial found that PTNS was noninferior to medication treatment at 12 weeks.

Maintenance Course of Percutaneous Tibial Nerve Stimulation
For individuals who have OAB syndrome who have failed behavioral and pharmacologic therapy, respond to an initial course of PTNS, and then receive maintenance 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 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 PTNS. PTNS may allow such individuals to avoid more invasive interventions. Adverse events appear to be limited to local irritation for both short- and long-term PTNS use.

Neurogenic Bladder Dysfunction
Clinical Context and Therapy Purpose
The purpose of PTNS in patients who have neurogenic bladder dysfunction is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of PTNS improve net health outcomes in patients with neurogenic bladder dysfunction?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest is patients 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 PTNS. 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 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 urinary tract infections.

SNS 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.

Timing
Outcomes are measured following the 12-week treatment regimen.

Setting
PTNS is administered in an outpatient clinical setting.

Systematic Reviews
Schneider et al (2015) published a systematic review on tibial nerve stimulation (transcutaneous and percutaneous) for treating neurogenic lower urinary tract dysfunction.[22] 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 transcutaneous tibial nerve stimulation (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).[23-26]

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

Fecal Incontinence
The Urgent PC Neuromodulation System is not cleared by the Food and Drug Administration for the treatment of fecal incontinence.

Clinical Context and Therapy Purpose
The purpose of PTNS in patients who have fecal incontinence is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of PTNS improve net health outcomes in patients with fecal incontinence?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest is patients with fecal incontinence.

Interventions
The therapy being considered is PTNS. 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 with fecal incontinence: conservative therapies (e.g., medical management, retraining of pelvic floor and abdominal wall musculature, dietary changes), medications, and SNS.

SNS 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 improvement is reported after 2 weeks, 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 (e.g., self-reported assessment of symptoms, a decrease in number of voids per day) and improved quality of life.

Timing
Outcomes are measured following the 6- to 12-week treatment regimen.

Setting
PTNS is administered in an outpatient clinical setting.

Systematic Reviews
Simillis et al (2018) conducted a systematic review and meta-analysis comparing PTNS with SNS for the treatment of fecal incontinence.[27] The literature search identified 4 studies (1 RCT, 3 nonrandomized prospective studies) including 302 patients (109 undergoing SNS, 193 undergoing PTNS). The Cochrane Collaboration's risk of bias tool was used to assess study quality. Because none of the studies blinded participants and personnel, the risk of performance and detection biases were high. Attrition and publication biases were not detected. Meta-analysis showed that patients undergoing SNS experienced significant improvements compared with patients undergoing PTNS as measured on the Wexner Fecal Incontinence Score (weighted mean difference, 2.3; 95% CI, 1.1 to 3.4) and fecal incontinence episodes per week (weighted mean difference, 8.1; 95% CI, 4.1 to 12.1).

Edenfield et al (2015) conducted a literature search through November 2013 and identified 17 studies (4 RCTs, 13 case series) on the use of tibial nerve stimulation (percutaneous and transcutaneous) for the treatment of fecal incontinence.[28] Three of the RCTs evaluated transcutaneous electrical nerve stimulation and the other PTNS. The 1 RCT and 4 case series using PTNS reported significant decreases in weekly fecal incontinence episodes following 12 weeks of treatment. The quality of life domain scores (e.g., depression, embarrassment, coping, lifestyle) showing significant improvements differed across the PTNS studies.

Horrocks et al (2014) conducted a literature search through February 2013 and identified 12 articles, 6 related to PTNS, 5 related to transcutaneous nerve stimulation, and 1 comparing both methods.[29] One RCT, by George et al (2013),[30] discussed below, was included in the Horrocks et al (2014) and the Edenfield et al (2015) reviews. Horrocks et al (2014) identified 5 case series and an RCT that reported the outcome of 50% or greater reduction in the number of fecal incontinence episodes per week immediately after PTNS treatment. In these studies, a median of 71% of patients (range, 63%-82%) reported at least a 50% reduction in episodes. The Horrocks (2014) analysis did not report on control groups.

Randomized Controlled Trials
George et al (2013) published the first sham-controlled trial.[30] Thirty patients (28 women) who had failed conservative therapy for fecal incontinence were randomized to PTNS (n=11), TTNS (n=11), or sham transcutaneous stimulation (n=8). Patients in all groups received a total of 12 treatments given twice weekly for 6 weeks. (This differed from the PTNS manufacturer's recommended course of 12 weekly treatments.) The primary study end point was at least a 50% reduction in the mean number of incontinence episodes per week at the end of the 6-week treatment period. Only 1 patient failed to complete the trial, and data were analyzed on an intention-to-treat basis. Nine of 11 patients in the PTNS group, 5 of 11 in the TTNS group, and 1 of 8 in the sham group attained the primary end point (p=0.035). The mean number of incontinence

episodes per week (standard deviation) at the end of the study was 1.8 (0.8), 5.1 (4.2), and 4.7 (3.5) in the PTNS, transcutaneous nerve stimulation, and sham groups, respectively (p=0.04). These findings are limited by the small sample size and short-term follow-up.

A large sham-controlled randomized trial, known as CONFIDeNT, was by Knowles et al (2015).[31] The trial was double-blind and multicenter. A total of 227 patients with fecal incontinence sufficiently severe to warrant intervention (according to the principal investigator at each site) were randomized to PTNS (n=115) or sham stimulation (n=112). Both groups received 12 weekly, 30-minute sessions. The primary outcome was at least a 50% reduction in the mean number of episodes of fecal incontinence per week compared with baseline. The mean number of episodes was calculated from 2-week bowel diaries. Twelve patients withdrew from the trial. After treatment, 39 (38%) of 103 in the PTNS group and 32 (31%) of 102 in the sham group had at least a 50% reduction in the number of fecal incontinence episodes per week. The difference between groups was not statistically significant (adjusted odds ratio, 1.28; 95% CI, 0.72 to 2.28; p=0.396). There was also no significant difference between the PTNS and sham groups in the proportion of patients achieving more than 25%, more than 75%, or 100% reduction in mean weekly episodes. There was, however, a significantly greater reduction in the absolute mean number of weekly fecal incontinence episodes in the PTNS group. The mean number of weekly fecal incontinence episodes in the PTNS group was 6.0 at baseline and 3.5 after treatment compared with 6.9 and 4.8, respectively, in the sham group (mean difference, -2.26; 95% CI, -4.18 to -0.35; p=0.021).

Horrocks et al (2017) conducted a post hoc analysis of data from the CONFIDeNT trial, to evaluate factors associated with the efficacy of PTNS for fecal incontinence.[32] Results from the multivariable logistic regression on the outcome of 50% improvement in weekly fecal incontinence episodes found that age, fecal urgency, stool consistency, and severity of fecal incontinence did not affect response to PTNS. Presence of obstructive defecation was the only variable that negatively affected response to PTNS (odds ratio, 0.4; 95% CI, 0.2 to 0.9). Excluding patients with obstructive defecation (n=112) resulted in a significant effect of PTNS compared with sham (49% vs 18%, p=0.002).

Thin et al (2015) published data on PTNS vs SNS for fecal incontinence.[33] Forty women were randomized, 17 to PTNS and 23 to SNS. Patients in the PTNS group had an initial course of 12 weekly sessions and received 3 maintenance treatments during the following 2 months. SNS was provided using a 2-stage approach: a test stimulation was conducted first, followed by permanent stimulation if they achieved a decrease in fecal incontinence episodes of at least 50% over the 2-week test period. The primary outcome was a reduction of at least 50% in fecal incontinence episodes per week (as determined by 2-week bowel diaries). Fifteen women passed temporary SNS and underwent permanent implantation. The proportion of patients who achieved the primary outcome at 6 months was 11 (61%) of 18 in the SNS group and 7 (47%) of 15 in the PTNS group. Rates at 3 months were 9 (47%) of 19 in the SNS group and 6 (38%) of 16 in the PTNS group. The authors did not conduct a direct statistical comparison of SNS and PTNS because the study was a pilot.

Nonrandomized Studies

Sanagapalli et al (2018) conducted a retrospective chart review of consecutive patients with multiple sclerosis–related fecal incontinence who had failed conservative therapy and who were subsequently treated with PTNS.[34] Patients (N=33) received 8 weekly treatments of PTNS, with responders receiving an additional 4 weeks of treatment. Subjects were classified as responders based on the Wexner Fecal Incontinence Score if scores at the end of treatment were either half of the baseline score or if the score was less than 10. Twenty-six (79%) of the patients were classified as responders. Responders tended to be more symptomatic at baseline and had greater improvements in quality of life scores.

Section Summary: Treating Fecal Incontinence

Few RCTs evaluating PTNS for the treatment of fecal incontinence have been published to date. The available RCTs have not found a clear benefit of PTNS. Neither sham-controlled trial found that active stimulation was superior to sham for achieving the primary outcome of at least a 50% reduction in mean incontinence episodes. The larger sham-controlled randomized trial found a significantly greater decrease in absolute number of weekly incontinence episodes in the active treatment group, but the overall trial findings did not suggest the superiority of PTNS over sham treatment. A meta-analysis of 1 RCT and several observational studies reported that patients receiving SNS experienced significant benefits compared with patients receiving PTNS. A post hoc analysis of the larger trial suggested a subset of patients with fecal incontinence, those without concomitant obstructive defecation, might benefit from PTNS.

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 PTNS, the evidence includes randomized sham-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 SUmiT and the OrBIT trials are 2 key industry-sponsored RCTs. Systematic reviews that included these and other published trials have found short-term reductions in voiding dysfunction with PTNS. The largest, highest quality study was the double-blinded, sham-controlled SUmiT trial, which reported a statistically significant benefit of PTNS vs sham at 12 weeks. In an additional, small sham-controlled trial, a 50% reduction in urge incontinent episodes was attained in 71% of PTNS group compared with 0% in the sham group. The nonblinded OrBIT trial found that PTNS was noninferior to medication therapy at 12 weeks. Adverse events were limited to local irritation effects. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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

For individuals who have neurogenic bladder dysfunction who receive PTNS, the evidence includes several RCTs and a systematic review of RCTs and observational data. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Only a few RCTs evaluating tibial nerve stimulation for treating neurogenic bladder have been published to date, and all but one performed transcutaneous stimulation rather than PTNS. Studies varied widely in factors such as 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 the effects of the technology on health outcomes.

For individuals who have fecal incontinence who receive PTNS, the evidence includes several RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The available RCTs have not found a clear benefit of PTNS. Neither of the sham-controlled trials found that active stimulation was superior to sham for achieving the primary outcome, at least a 50% reduction in mean weekly fecal incontinence episodes. The larger sham-controlled randomized trial did find a significantly greater decrease in the absolute number of weekly incontinence episodes in the active treatment group, but the overall trial findings did not suggest the superiority of PTNS over sham treatment. A meta-analysis of a single RCT and several observational studies reported that patients receiving sacral nerve simulation experienced significant benefits compared with patients receiving PTNS. A post hoc analysis of the larger trial suggested a subset of patients with fecal incontinence (those without concomitant obstructive defecation) may benefit from PTNS. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical Input

Objective

In 2018, clinical input was sought to help determine whether the use of maintenance percutaneous tibial nerve stimulation for individuals with non-neurogenic urinary dysfunction including overactive bladder who have failed behavioral and pharmacologic therapy and respond to an initial course of percutaneous tibial nerve stimulation would provide a clinically meaningful improvement in the net health outcome and whether the use is consistent with generally accepted medical practice.

Respondents

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

- David A. Ginsberg,[a] MD, Urology, Female pelvic medicine & reconstructive surgery (FPMRS), University of Southern California identified by American Urological Association (AUA)
- Howard B. Goldman,[a] MD, Urology, Female pelvic medicine & reconstructive surgery (FPMRS) Cleveland Clinic identified by AUA
- Matthew P. Rutman, MD, Association Professor of Urology, Columbia University identified by Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU).

[a] Indicates that conflicts of interest related to the topic where clinical input is being sought were identified by this respondent (see Appendix).

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.

Clinical Input Responses

Clinical Indication	Respondent	Identified by	Confidence Level That Clinical Use Expected to Provide Clinically Meaningful Improvement in Net Health Outcome										Confidence Level that Clinical Use is Consistent with Generally Accepted Medical Practice									
			NO (High / Intermediate / Low)					YES (Low / Intermediate / High)					NO (High / Intermediate / Low)					YES (Low / Intermediate / High)				
			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 (see Appendix 1).

Additional Comments

- "In regards to duration we maintain patients on a monthly treatment. We do not give them leeway in regards to symptoms such that they might be stimulated more often." (Dr. Ginsberg identified by AUA)
- "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." (Dr. Goldman identified by AUA)
- "Management criteria would be once a week for 12 weeks and monthly afterward for maintenance." (Dr. Rutman identified by SUFU)

See Appendices 1 and 2.

Supplemental Information

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

In response to requests from Blue Cross Blue Shield Association, clinical input on use of maintenance percutaneous 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 was received from 3 physician respondents identified by specialty societies in 2018.

Based on the evidence and independent clinical input, the clinical input supports that the following indication provides a clinically meaningful improvement in the net health outcome and is consistent with generally accepted medical practice:

- Use of monthly 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.

2012 Input

In response to requests from Blue Cross Blue Shield Association, input was received through 3 physician specialty societies and 1 academic medical center in 2012. Input was mixed. There was no consensus or near-consensus that the policy should be changed. The range of opinions included that PTNS should be considered investigational, that it should be considered for use in medically refractory patients as second-line treatment, and that the evidence is sufficient to consider this treatment to be medically necessary.

Practice Guidelines and Position Statements

American Urological Association et al

The American Urological Association and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (2015) published guidelines on the diagnosis and treatment of non-neurogenic overactive bladder in adults.[35] The guidelines included a statement that clinicians may offer percutaneous tibial nerve stimulation (PTNS) as a third-line treatment option in carefully selected patients. The statement carried a grade C rating, indicating that the balance of benefits and risks/burdens are uncertain.

American College of Obstetricians and Gynecologists

The American College of Obstetricians and Gynecologists (2015) practice bulletin on the treatment of urinary incontinence in women did not address PTNS or other types of nerve stimulation.[36]

American Gastroenterological Association

The American Gastroenterological Association (2017) issued an expert review and clinical practice update on surgical interventions and device-aided therapy for the treatment of fecal incontinence.[37] The update stated that "until further evidence is available, percutaneous tibial nerve stimulation should not be used for managing FI [fecal incontinence] in clinical practice."

European Association of Urology

The European Association of Urology (2018) conducted a review of third-line therapies for patients with overactive bladder who do not respond to bladder training or pharmacotherapy.[38] The Association found that botulinum toxin, PTNS, and sacral nerve stimulation may be effective treatments for OAB. There was no high-quality evidence showing the superiority of one therapy over another. Age, comorbidities, patient preference, and surgical expertise were factors to be considered when treatment decisions are made. Table 7 compares the treatment options.

Table 7. Comparisons of SNM, PTNS, and Botulinum Toxin as Treatments for Overactive bladder

	SNM	PTNS	Botulinum Toxin Type A
FDA/EC approval	Yes	Yes	Yes
Long-term results	Yes	No	Limited
Advantages	• Minimally invasive • Effective for urinary and bowel disorders	• Noninvasive • Uncomplicated procedure	• Minimally invasive • Direct effect
Disadvantages	• Permanent implant • Battery replacement every 5-8 y	• May need to repeat procedure every 8-12 wk • Inferior efficacy	• Repeat after 6-12 mo • Need for CISC
Reversibility	Removal of implant	Instantly reversible	After 6 mo
Adverse events	• Wound infection • Device-related pain • Device malfunction	• None	• Urinary retention • Urinary tract infection • Hematuria

Adapted from Marcelissen et al (2018).[38]
CISC: clean intermittent self-catheterization; EC: European Commission; FDA: Food and Drug Administration; PTNS: percutaneous tibial nerve stimulation; SNM: sacral neuromodulation.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

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

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 8.

Table 8. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01162525	Percutaneous Tibial Nerve Stimulation (pTNS) for Patients With Fecal Urge Incontinence	100	Dec 2017 (ongoing)
NCT02299544	Safety and Performance of the BlueWind System for the Treatment of Patients With Overactive Bladder (OAB)	36	Aug 2018

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT02888899	Percutaneous Tibial Nerve Stimulation in Combination With Biofeedback in Patients With Fecal Incontinence - A Randomized Controlled Trial	Unknown	Mar 2019
NCT03547518	Sham Controlled Trial of Rapid Induction Percutaneous Tibial Nerve Stimulation	64	May 2020
NCT02190851	Evaluation of Treatment by Transcutaneous Electrical Nerve Stimulation (TENS) of the Posterior Tibial Nerve for Lower Urinary Tract Disorders in Parkinson's Syndrome	220	Dec 2020
Unpublished			
NCT02657057	Effects of Transcutaneous and Percutaneous PTNS on Idiopathic OAB	68	Mar 2017 (completed)
NCT01940367	Percutaneous Tibial Nerve Stimulation vs. Transcutaneous Electrical Nerve Stimulation for Overactive Bladder: A Randomized Trial	114	Dec 2017 (unknown)

NCT: national clinical trial.

Appendix

Appendix 1: Clinical Input

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 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.

Appendix 2: Clinical Input Responses

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.

Responses

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 regards 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

No.	Rationale
	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 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

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 regards 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	

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Documentation for Clinical Review

Please provide the following documentation (if/when requested):

- History and physical and/or consultation notes including:
  - Clinical findings (i.e., pertinent symptoms and duration)
  - Reason for procedure
  - Pertinent past procedural history
  - Prior conservative therapies (e.g. behavioral and pharmacologic), duration, and response
  - Documented improvement of urinary dysfunction meeting treatment goals (for maintenance therapy)

Post Service

- Procedure report(s)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

MN/IE

The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

Type	Code	Description
CPT®	64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming
	64999	Unlisted procedure, nervous system
	97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)
	97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes
HCPCS	None	
ICD-10 Procedure	01HY3MZ	Insertion of Neurostimulator Lead into Peripheral Nerve, Percutaneous Approach

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
02/27/2015	Policy title change from Urinary Incontinence Outpatient Treatment BCBSA Medial Policy adoption Policy revision with position change	Medical Policy Committee
03/01/2016	Policy revision without position change	Medical Policy Committee
12/01/2017	Policy revision without position change	Medical Policy Committee
08/01/2018	Policy revision with position change	Medical Policy Committee
10/01/2018	Policy revision without position change	Medical Policy Committee

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.