Comparators
The following therapies are currently being used to make decisions about neurogenic bladder dysfunction: conservative treatments (eg, 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 (eg, maximum cystometric capacity, maximum detrusor pressure). None of the RCTs reported statistically significant between-group differences in clinical outcome variables (eg, 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 (eg, 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 (eg, 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 (eg, 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: Yes or No	NO: High 5	4	Intermediate 3	2	Low 1	YES: Low 1	Intermediate 2	3	4	High 5	Confidence Level that Clinical Use is Consistent with Generally Accepted Medical Practice: Yes or No	NO: High 5	4	Intermediate 3	2	Low 1	YES: Low 1	Intermediate 2	3	4	High 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, 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 while this policy was under review 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, input was received through 3 physician specialty societies and 1 academic medical center while this policy was under review 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
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	220	Dec 2020

	Parkinson's Syndrome		
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.

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Billing Coding/Physician Documentation Information

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
L8679	Implantable neurostimulator, pulse generator, any type

	ICD10 Codes
N32.81	Overactive bladder
N39.41-N39.498	Other specified urinary incontinence code range
R33.0-R33.9	Retention of urine code range
R35.0	Frequency of micturition
R39.15	Urgency of urination

Prior to 2011, the correct CPT code to use for PTNS needle insertion is the unlisted CPT code 64999. CPT codes for percutaneous implantation of neurostimulator electrodes (i.e., 64553-64565) are not appropriate since PTNS uses percutaneously inserted needles and wires rather than percutaneously implanted electrodes. The stimulation devices used in PTNS and PNT are not implanted, so CPT code 64590 is also not appropriate.

Additional Policy Key Words

N/A

Policy Implementation/Update Information

5/1/08	New policy; considered investigational.
5/1/09	No policy statement changes.
5/1/10	No policy statement changes.

9/1/10	Coding updated.
1/1/11	Coding updated.
5/1/11	No policy statement changes.
11/1/11	No policy statement changes.
5/1/12	No policy statement changes.
11/1/12	Policy statement revised to add neurogenic bladder to list of investigational indications.
5/1/13	No policy statement changes.
11/1/13	No policy statement changes.
5/1/14	No policy statement changes.
11/1/14	No policy statement changes.
5/1/15	Title changed to "Percutaneous Tibial Nerve Stimulation." "Posterior" changed to "percutaneous" in existing policy statement. Policy statement edited to investigational for all indications with bullet points for urinary and fecal incontinence.
11/1/15	No policy statement changes.
5/1/16	No policy statement changes. Added CPT 64999 and 97032
11/1/16	No policy statement changes.
5/1/17	No policy statement changes.
12/1/17	Revised policy statements for use of PTNS in OAB syndrome which has failed behavioral and pharmacologic therapy. In these patients, PTNS is considered medically necessary as initial course of therapy and maintenance therapy for individuals who respond to initial course.
6/1/18	Updated second Medically Necessary statement wording: Maintenance therapy using monthly percutaneous tibial nerve stimulation is considered medically necessary for individuals following a 12-week initial course of percutaneous tibial nerve stimulation that resulted in improved urinary dysfunction meeting treatment goals. Added "dysfunction" to Investigational statement
11/1/18	No policy statement changes.

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 (eg, 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 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	Yes					X

	who respond to an initial course of PTNS		
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	