Anthem

Clinical UM Guideline

Subject: Sacral Nerve Stimulation and Percutaneous or Implantable Tibial Nerve Stimulation for Urinary and Fecal Incontinence; Urinary Retention
Guideline #: CG-SURG-95 **Publish Date:** 12/28/2023
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Description

This document addresses sacral nerve stimulation (SNS), percutaneous tibial nerve stimulation (PTNS), and implantable tibial nerve stimulation in individuals with urinary retention or chronic, refractory urinary and fecal incontinence.

Urinary incontinence is the inability to hold urine in the bladder and can be due to loss of voluntary control over the urinary sphincters resulting in the involuntary passage of urine. Urinary retention is the inability to completely empty the bladder. Fecal incontinence (FI) is a chronic inability to control bowel function for elimination.

Note: This document does not address the use of SNS for the treatment of *neurogenic bladder* secondary to spinal cord injury. For information about treatment of neurogenic bladder, see:

- CG-SURG-08 Sacral Nerve Stimulation as a Treatment of Neurogenic Bladder Secondary to Spinal Cord Injury

Note: This document does not address the use of *transcutaneous* tibial nerve stimulation. For information about *transcutaneous* tibial nerve stimulation, see:

- CG-DME-04 Electrical Nerve Stimulation, Transcutaneous, Percutaneous

Note: Please see the following related documents for additional information:

- MED.00125 Biofeedback and Neurofeedback
- SURG.00010 Treatments for Urinary Incontinence
- SURG.00056 Transanal Radiofrequency Treatment of Fecal Incontinence
- SURG.00102 Artificial Anal Sphincter for the Treatment of Severe Fecal Incontinence

Note: The use of physical therapy and botulinum toxin is not addressed in this document. Refer to applicable guidelines used by the plan.

Clinical Indications

Medically Necessary:

I. Sacral Nerve Stimulation for Urinary Urge Incontinence, Urgency/Frequency, and Retention

A trial or temporary sacral nerve stimulator is considered **medically necessary** when the following criteria are met (A *and* B):

A. Any of the following are present and not due to a neurological condition:
   1. Urinary urge incontinence; **or**
   2. Urinary urgency/frequency; **or**
   3. Non-obstructive urinary retention;
   and
B. Criteria 1 *and* 2 are met:
   1. Clinically significant symptoms are present (for example, frequency or severity impacts ability to work or participate in activities outside of the home); **and**
   2. Symptoms are refractory to, or individual could not tolerate, conservative treatment (for example, medication, pelvic floor muscle exercises, pelvic floor physical exercises with biofeedback, bladder training, or intermittent catheterizations for non-obstructive urinary retention) for at least a sufficient duration to fully assess treatment effect.*

A permanent sacral nerve stimulator is considered **medically necessary** when criteria A *and* B are met:

A. The individual has met criteria above for a trial or temporary sacral nerve stimulator;**and**
B. The individual has demonstrated a successful trial of the temporary sacral nerve stimulator, defined as:
   1. For urinary urge incontinence: At least 50% reduction in one of the following: daily incontinence episodes, severity of the episodes, or the number of pads/diapers used per day; **or**
   2. For urinary urgency/frequency: At least 50% reduction in the number of voids daily, or 50% increase in volume voided per void; **or**
   3. For urinary retention: At least a 50% reduction in catheter volume/catheterization.

*** Note:** The time frame for prior conservative treatment measures to demonstrate a refractory response is generally considered to be 2 to 3 months' duration, subject to individual variability.

II. Sacral Nerve Stimulation for Fecal Incontinence

A trial or temporary sacral nerve stimulator is considered **medically necessary** when the following criteria are met (A *and* B):

A. Treatment is for fecal incontinence; **and**
B. The following are met (1 *and* 2):
   1. Incontinent episodes average greater than or equal to 2 per week for 6 months;** **and**
   2. Symptoms are refractory to, or individual could not tolerate, conventional therapy (for example, dietary modification, addition of bulking agents, pharmacologic treatment) for at least a sufficient duration to fully assess treatment effect.*

A permanent sacral nerve stimulator is considered **medically necessary** when the following criteria are met:

A. The individual has met the criteria above for a trial or temporary sacral nerve stimulator;**and**
B. The individual has had a successful trial of the temporary sacral nerve stimulator, defined as at least a 50% improvement in symptoms.

Notes:
* The time frame for prior conservative treatment measures to demonstrate a refractory response is generally considered to be 2 to 3 months' duration, subject to individual variability.
** After vaginal childbirth, most individuals who experience fecal incontinence in the immediate postpartum period will see improvement in symptoms in the year following delivery.

III. Replacement and Revision of Sacral Nerve stimulators

Replacement or revision of an implanted sacral nerve stimulator (with or without lead changes) is considered **medically necessary** when the current implanted device is no longer functioning appropriately.

Not Medically Necessary:

A. A sacral nerve stimulator is considered **not medically necessary** when the medically necessary criteria above have not been met.

Replacement or revision of an implanted sacral nerve stimulator is considered **not medically necessary** when the medically necessary criteria above for replacement or revision have not been met.

IV. Percutaneous or Implantable Tibial Nerve Stimulation

Medically Necessary:

An initial 12-week trial of *percutaneous* tibial nerve stimulation is considered **medically necessary** when the following criteria are met (A *and* B):

A. Any of the following are present for at least 3 months, and not due to a neurological condition:
    1. Urinary urge incontinence; **or**
    2. Urinary urgency/frequency; **or**
    3. Non-obstructive urinary retention;
    and
B. Criteria 1 and 2 below are met:
    1. Clinically significant symptoms are present (for example, frequency, or severity impacts ability to work or participate in activities outside of the home); **and**
    2. Symptoms are refractory to, or individual could not tolerate, conservative treatment (for example, medication, pelvic floor muscle exercises, pelvic floor physical exercises with biofeedback, bladder training, or intermittent catheterizations for non-obstructive urinary retention) for at least a sufficient duration to fully assess treatment effect.*

*** Note:** The time frame for prior conservative treatment measures to demonstrate a refractory response is generally considered to be 2 to 3 months' duration, subject to individual variability.

Continuation of *percutaneous* tibial nerve stimulation with monthly treatment is considered medically necessary when the following criteria are met (A *and* B):

A. An initial 12-week trial demonstrated improved urinary dysfunction meeting treatment goals, defined as:
    1. For urinary urge incontinence: At least 50% reduction in one of the following: daily incontinence episodes, severity of the episodes, or the number of pads/diapers used per day; **or**
    2. For urinary urgency/frequency: At least 50% reduction in the number of voids daily, or 50% increase in volume voided per void; **or**
    3. For urinary retention: At least a 50% reduction in catheter volume/catheterization.
    and
B. Annual evaluation indicates that the condition for which the treatment was initiated is still present.

An *implantable* tibial nerve stimulator is considered medically necessary for individuals when the (A *and* B) criteria are met (A *and* B):

A. The individual has met criteria above for evaluation for a temporary percutaneous tibial nerve stimulator;**and**
B. The individual has demonstrated a successful response to a percutaneous tibial nerve stimulation defined as:
    1. For urinary urge incontinence: At least 50% reduction in one of the following: daily incontinence episodes, severity of the episodes or the number of pads/diapers used per day; **or**
    2. For urinary urgency/frequency: At least 50% reduction in the number of voids daily, or 50% increase in volume voided per void; **or**
    3. For urinary retention: At least a 50% reduction in catheter volume/catheterization.

Replacement or revision of a percutaneous or implantable tibial nerve stimulator (with or without lead changes) is considered **medically necessary** when the current implanted device is no longer functioning appropriately.

Not Medically Necessary:

Percutaneous or implantable tibial nerve stimulation is considered **not medically necessary** when the medically necessary criteria above have not been met.

Replacement or revision of a percutaneous or implantable tibial nerve stimulator is considered **not medically necessary** when the medically necessary criteria above for replacement or revision have not been met.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. 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.

Sacral Nerve Stimulation
When services may be Medically Necessary when criteria are met:

CPT

64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64581	Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
0786T	Insertion or replacement of percutaneous electrode array, sacral, with integrated neurostimulator, including imaging guidance, when performed
0787T	Revision or removal of neurostimulator electrode array, sacral, with integrated neurostimulator
	For the following CPT codes **when specified as a sacral nerve stimulator**:
64585	Revision or removal of peripheral neurostimulator electrode array [*when specified as a sacral nerve stimulator*]
64590	Insertion or replacement of peripheral, sacral or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver [*when specified as sacral nerve stimulator*]

HCPCS

	For the following HCPCS codes **when specified as sacral nerve stimulator**:
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1883	Adapter/extension, pacing lead or neurostimulator lead (implantable)
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension

ICD-10 Procedure

	For the following codes **when specified as sacral nerve stimulator leads**:
01HY0MZ	Insertion of neurostimulator lead into peripheral nerve, open approach
01HY3MZ	Insertion of neurostimulator lead into peripheral nerve, percutaneous approach
01HY4MZ	Insertion of neurostimulator lead into peripheral nerve, percutaneous endoscopic approach

ICD-10 Diagnosis

N32.81	Overactive bladder
N39.41-N39.498	Other specified urinary incontinence
R15.0-R15.9	Fecal incontinence
R33.0-R33.9	Retention of urine
R35.0-R35.89	Polyuria
R39.11-R39.198	Other difficulties with micturition

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met or for all other diagnoses not listed.

Percutaneous or Implantable Tibial Nerve Stimulation
When services may be Medically Necessary when criteria are met:

CPT

64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming
0587T	Percutaneous implantation or replacement of integrated single device neurostimulation system for bladder dysfunction including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve
0588T	Revision or removal of percutaneously placed integrated single device neurostimulation system for bladder dysfunction including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve
0816T	Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (eg, array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subcutaneous
0817T	Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (eg, array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subfascial
0818T	Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subcutaneous
0819T	Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subfascial

ICD-10 Diagnosis

N32.81	Overactive bladder
N39.41-N39.498	Other specified urinary incontinence
R33.0-R33.9	Retention of urine
R35.0-R35.89	Polyuria
R39.11-R39.198	Other difficulties with micturition

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met or for all other diagnoses not listed.

Discussion/General Information

Sacral Nerve Stimulation (SNS)

A sacral nerve stimulator (SNS) is a device that is surgically implanted to treat urinary or fecal incontinence. Use of an SNS includes both a test phase and a second-stage implantation phase.

The Test phase involves implantation of a temporary SNS device for a trial period of sacral nerve neuromodulation. This may use either percutaneous nerve stimulation or a temporarily implanted device. This procedure is to confirm the integrity of the peripheral nerves, the feasibility of SNS therapy, to identify the optimal site for a temporary SNS, and to determine anticipated response and candidacy for a permanent device. During the trial, the individual maintains a voiding diary to document their symptoms at baseline and then daily for a one- to two-week period while the device is active. The temporary device includes a portable external stimulator, which is carried in the pocket or attached to a belt. The results of the test phase are used to determine whether individuals are appropriate candidates for the permanent SNS device. Pivotal clinical studies assessed both 50% reduction in frequency and 50% increase in volume void per void as endpoints. The rate of adverse events due to SNS is reported as high, and include post-implant pain, infection, adverse changes in bowel function, lead migration, and electric shock sensation. However, most events are minor and resolve with treatment or adjustment to the device.

The InterStim™ System for Urinary Control (Medtronic, Inc., Minneapolis, MN), was investigated in a large multicenter, randomized clinical trial (RCT)that demonstrated that the device was effective in significantly reducing urinary symptoms in those with urge incontinence, urgency/frequency and non-obstructive urinary retention (Hassouna, 2000; Schmidt, 1999). The device was originally cleared by the Food and Drug Administration (FDA) in 1998 for urinary incontinence and received additional labeled clearance for urinary retention in 1999. Additional updated models have obtained FDA clearances; including the Medtronic InterStim Micro rechargeable sacral neuromodulation (SNM) system, which was cleared for the treatment of urge incontinence, urgency/frequency, non-obstructive urinary retention, and chronic fecal incontinence in persons who have failed, or are not candidates for, more conservative treatments (FDA, 2020).

SNS for Urinary incontinence

In May 2012, the American Urological Association (AUA) and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) published *Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults*and addressed SNS as a recommendation. This document was reissued in 2014 and amended in 2019 with an updated literature review but no change to the recommendation for SNS, as follows:

> Clinicians may offer sacral neuromodulation (SNS) as third-line treatment in a carefully selected patient population characterized by severe refractory OAB (overactive bladder) symptoms or patients who are not candidates for second-line therapy and are willing to undergo a surgical procedure. *Recommendation** (Evidence strength – Grade C; Benefits outweigh risks/burdens) (Lightner, 2019).

This determination was based upon the following guideline discussion:

> Given the negative effects on quality of life associated with severe incontinence and frequency, the Panel judged that benefits of SNS in the appropriate patient outweighed the risks/burdens and notes that patients should be carefully counseled regarding the risks/burdens. Evidence strength is Grade C because of the predominance of observational designs, the small sample sizes, the limited number of unique patient groups (i.e., there are multiple reports on the same patient groups followed over time) and limited information regarding the protocols used by patients to maintain symptom control.

***Note:** According to the AUA, use of the nomenclature, “Recommendation” is defined as:

> Recommendation: Directive statement that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be taken based on Grade C (low quality; low certainty) evidence.

It was further noted in the updated literature review that:

> SNS studies reported frequent adverse events, including pain at the stimulator site (3.3 to 19.8% of patients), pain at the lead site (4.5 to 19.1% of patients), lead migration (1.1 to 2.2, 8.6% of patients), infection/irritation (2.2 to 14.30% of patients), electric shock (5.5 to 10.2, 7.9% of patients) and need for surgical revision (6.25 to 39.5% of patients). In most studies, the need for surgical revision occurred in greater than 30% of patients (Gormley, 2014).

On November 13, 2019 the Axonics Sacral Neuromodulation (SNM) System (Axonics Modulation Technologies, Inc. Irvine, CA) was cleared by the FDA for, “The treatment of urinary retention and the symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency alone or in combination, in patients who have failed or could not tolerate more conservative treatments.” This clearance was subject to periodic post-approval safety reports to be submitted to the FDA.

SNS for Fecal incontinence

The Food and Drug Administration (FDA) cleared the Interstim Therapy (Medtronic, Inc., O’Fallon, IL) device for the application of the treatment of fecal incontinence on March 14, 2011, subject to a 5-year post-approval study with the primary objective to continue evaluation of incontinent episodes per week at yearly intervals through 5 years post-implant. Both device and therapy adverse events were tracked during this study period. In 2011, Mellgren and colleagues submitted some ongoing results for the FDA post approval study. A total of 83 participants completed part or all of the assessment. Perfect continence was reported by 40% of study participants. Improvements in the Fecal Incontinence Quality of Life scale were reported at 12, 24 and 36 months of follow-up. Adverse events included implant site pain (28%), paresthesia (15%), change in the sensation of stimulation (12%), and infection (10%). The authors stated 77 of 120 participants (64%) completed a bowel diary assessment at the 3-year follow-up. While there were a large number of trial subjects who were lost to follow-up (n=43), there was good continence control noted in 40% of trial participants.

On September 6, 2019 the FDA cleared another device, the Axonics r-SNM® System, which is another rechargeable SNM system. This device is indicated for, “The treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments.” This approval is contingent upon submissions of annual safety reports including any adverse events associated with the device (FDA, 2019).

Wexner and colleagues (2010) reported results from a prospective, multicenter study of SNS for fecal incontinence. Inclusion criteria were refractory fecal incontinence averaging 2 episodes per week for 6 months or for 12 months after vaginal delivery. Excluded were those who had previous rectal surgery, if performed within the last 12 months (or within 24 months in cases of cancer); defects of the external anal sphincter over 60 degrees; chronic inflammatory bowel disease; visible sequelae of pelvic radiation; active anal abscesses and fistulae; neurologic diseases such as clinically significant peripheral neuropathy or complete spinal-cord injury; and anatomic limitations preventing the successful placement of an electrode. Out of 285 participants evaluated, 120 participants underwent preliminary test stimulation procedures and showed a greater than or equal to 50% improvement. This group went on to receive a permanent stimulator. A 50% or better improvement was seen in 106 participants at 12 months, 67 participants at 24 months and 30 participants at 36 months, based on records of incontinent episodes. Further analysis showed that 40% of the 106 participants at the 12-month follow-up reported complete continence.

In 2022, Chartier-Kastler reported the 3-year results of the SOUNDS (Sacral neuromOdUlation with InterStim therapy for intractable lower uriNary tract DySfunctions) prospective observational study involving 291 subjects with OAB treated with SNS. Subjects included those with urge-frequency (dry) and urinary urge incontinence (wet) OAB. Subjects received a de novo (n=139) or replacement (n=51) InterStim device and had four follow-up visits two within the first year and annually thereafter. A fourth follow-up visit was achieved by 190 subjects after a mean of 33.7 months. Both the mean number of voids per day for the dry OAB group and leaks per day for the wet OAB group were significantly lower at all follow-up visits, except at 21 months for the dry OAB subjects who received a replacement device subgroup (p=0.05). Therapy responder rates in the UI cohort at 34 months were 72% and 86% in the de novo and replacement groups, respectively, and complete continence was achieved in 30% of the de novo group and 50% of the replacement group. There were statistically significant improvements in the OAB-specific domain of the Urinary Symptom Profile (USP2) at all visits for both the de novo and replacement groups (all p<0.001). The device- or procedure-related adverse event rate was 49%, with the most frequent events reported being implant site pain (6%), implant site infection (4%), battery-related events (5%), device use error (5%), and device failure (7%). The most frequent action taken to address adverse events was reprogramming of the device. Overall, 12% of subjects experienced a serious adverse event, which were most frequently addressed by removal of the lead (11%) or neurostimulator (8%), reprogramming the device (7%), or antibiotic (6%) or analgesic treatment (4%). Surgical revisions, including replacement, repositioning, or temporary or permanent removal of one or more components of the system was reported in 33% of subjects who had received a full system. Permanent device removal occurred in 13% of subjects. The authors concluded that SNS resulted in significant reductions in both daily voids and leaks subjects with OAB. They also stated, “the therapy safety profile was in agreement with published literature. Although the majority of ADEs were classified as minor, this remains an area for which further improvements are desirable through procedural modifications and technical advances.”

While the literature supports SNS for fecal incontinence, the adverse event occurrence is high. Additionally, degree of success varies among the eligible population. Careful selection of individuals for this treatment is important (Mowat, 2008). Information regarding the benefits and risks should be discussed so that suitable individuals can make an informed decision. It is notable that most individuals who experience fecal incontinence in the immediate postpartum period will see improvement in symptoms in the year following delivery and can avoid treatment with SNS.

Percutaneous Tibial Nerve Stimulation (PNTS)

Percutaneous tibial nerve stimulation (PTNS) involves a battery powered external electrical pulse generator and a needle electrode lead set. The needle probe is implanted in the tibial nerve and is attached to the electrical pulse generator. This minimally invasive neuromodulation system was developed as a less-invasive alternative to SNS. It is designed to deliver retrograde access to the sacral nerve through percutaneous electrical stimulation of the tibial nerve. The Urgent PC System was initially cleared by the FDA in 2005 and is intended, “To treat patients with overactive bladder and associated symptoms of urinary urgency, urinary frequency, and urge incontinence” (FDA, 2005).

PTNS treatment includes a 12-week initial treatment phase followed by an indefinite maintenance treatment phase, with each of these phases having different treatment protocols. The initial treatment phase consists of 1 to 3 weekly 30-minute treatment sessions for 12 weeks

The Urgent PC Neuromodulation System (Uroplasty, Inc., Minnetonka, MN) received FDA 510k clearance on August 20, 2007 for treatment of those with urinary urgency, urinary frequency, and urge incontinence.

PTNS for Urinary incontinence

Peters and colleagues (2009a) identified a scientific and clinical need to test PTNS in a controlled clinical trial since most drug or device studies investigating voiding dysfunction have a large placebo effect. They conducted a randomized, blinded control study testing a proposed realistic sham against PTNS on 30 healthy subjects. The participants were blinded when given PTNS stimulation and TENS stimulation (sham). The TENS stimulation was modified to mimic PTNS. In total, 10/30 (33%) of the shams were identified correctly. From this study, the authors concluded that subjects are unable to identify whether they are receiving a sham or the PTNS and that this protocol provides a reasonable sham for PTNS controlled studies.

Peters and colleagues (2009b) also conducted an industry supported, unblinded, randomized trial comparing PTNS and extended-release tolterodine (Detrol LA) in women with overactive bladder syndrome. Subjects had to have symptoms of overactive bladder (OAB) with at least 8 voids per 24 hours; the mean daily voids for those entering the study were 12.3. The primary outcome was the non-inferiority of PTNS in the mean reduction in the number of voids per 24 hours after 12 weeks of treatment. Study findings showed non-inferiority of PTNS based on results for 84 participants. The decrease in voids per day was 2.4 in the PTNS group and 2.5 in the tolterodine group. There was a statistically significant difference in the proportion of those reporting improvement or cure in symptoms (79.5 vs. 54.8%). Limitations of this study include the lack of blinding of participants and providers, as well as lack of a sham/placebo group both to mitigate the potential bias, due to subjective outcomes, and to evaluate whether either treatment is better than placebo. Another limitation is that it reports on short-term efficacy only.

In 2010, MacDiarmid and colleagues reported on those with successful PTNS (responders) who were studied for 12 weeks in a previous study (Peters, 2009). Thirty-three PTNS responders continued therapy with 32 and 25 subjects completing 6 and 12 months of therapy, respectively. Subjects received a mean of 12.1 treatments during an average of 263 days, with a mean of 21 days (median 17) between treatments. Results were reported as subject global response assessments which showed sustained improvement from 12 weeks at 6 and 12 months, with 94% and 96% of responders, respectively. OAB symptom improvements including frequency, nocturia, urgency, voided volume and urge incontinence episodes were sustained for all outcomes from 12 weeks through 6 and 12 months. At 6 and 12 months, all voiding diary (6 months n=30; 12 months n=25) parameters showed statistically significant improvements in mean values compared to baseline. Although the study showed significant improvements in continence, its small size is a drawback. The authors reported that 1 subject withdrew prior to the 6-month assessment and those who withdrew after the 6-month interval (n=7), were considered improved at the last assessment evaluation. Using Last-Observation-Carried-Forward (LOCF) can introduce a biased estimate of the treatment effect.

In another study, Peters and colleagues (2010) described a multicenter, double-blinded, randomized controlled trial evaluating the efficacy of PTNS to inactive sham therapy in participants with overactive bladder (OAB) symptoms (SUmiT trial). A total of 220 participants were randomized in a 1:1 ratio, one group (n=110) receiving PTNS and the other group (n=110) receiving sham treatment for 30 minutes, once a week, for 12 weeks. OAB quality of life questionnaires and 3-day voiding diaries began at baseline and were completed at week 13. Global response assessments were also compiled at week 13. Results showed a significant improvement in bladder symptoms in the PTNS group (54.4%) vs. the sham group (20.9%) from baseline (p≤0.001). Individual voiding diaries also showed statistically significant improvements in urinary frequency, nighttime voiding, urgency and incontinent episodes. Adverse events such as ankle bruising, bleeding and needle site discomfort only occurred in the PTNS group. No adverse effects occurred in the sham group. While the study demonstrated improvements using PTNS, its limitation was the short-term follow-up. Further, the authors only described the participant blinding in this double-blinded study.

Peters and colleagues (2012) reported 24 month outcomes of the STEP study, (the Sustained Therapeutic Effects of Percutaneous

Tibial Nerve Stimulation), which was an extension of the SUmiT trial. Of the 50 positive responders to the SUmiT trial enrollment, 35 continued until 24 months. Outcome measures included those from the SUmiT trial - voiding diaries, urinary frequency, urge incontinence, nighttime voids and moderate to severe urgency. The authors noted that voiding diary parameters displayed non-normality at some time points, so median values were reported for consistency using Intent-to-Treat with Last Value Carried Forward (ITT-LVCF) analysis. Using this analysis, the authors found no statistical evidence of significant differences in voiding diary parameter improvements between those continuing to 24 months and those who exited the study early. ITT-LVCF analysis also showed significant improvement in symptom severity, Health Related Quality of Life (HR QoL), OAB-q (questionnaire) and GRA (Global Response Assessment). The authors stated there were no adverse events; however, 4 participants reported urinary tract infections, pulling sensation at the feet, bladder pressure, pinched nerve and slow stream. One additional subject reported two separate instances of mild treatment-related bleeding at the needle site during follow-up. Three year outcomes data were reported in 2013, in which only 29 of the original 60 participants eligible for the STEP trial (58%) completed the protocol through 36 months of follow-up. Among these 29 study completers, the median number of PTNS treatments per month (from 6 to 36 months) was 1.0 (Interquartile range 0.9-1.2). The investigators concluded that 97% met the primary efficacy endpoint of moderate or marked improvement in overall bladder symptoms according to the GRA compared to baseline. ITT-LVCF and Bayesian analyses of the GRA reached the same conclusion at 36 months (LVCF-ITT: 76%; Bayesian: 77%). OAB-q HR QoL and symptom severity scores remained improved throughout the study at all follow-up visits (all $p<0.0001$). A treatment-tapering protocol was utilized whereby subjects would self-schedule subsequent PTNS treatments when symptoms of OAB returned, which was determined by the authors to demonstrate the long-term durability of the therapeutic effect. However, the 3-year results of the STEP study were limited by small sample size, a high attrition rate and the lack of reporting study outcomes in the control group. This flaw in the study design, along with the large loss to follow-up, makes it difficult to draw conclusions regarding the overall clinical efficacy of PTNS (Peters, 2013).

In 2011, the FDA issued a guidance document entitled, Clinical Investigations of Devices indicated for the Treatment of Urinary Incontinence, in which it was noted that major challenges exist in designing objective clinical studies to investigate the safety and effectiveness of UI devices, “Including the inherent variability and subjectivity of the typical outcome measures commonly used to assess the device effectiveness, the significant placebo effect associated with some of these outcome measures, and the heterogeneous nature of the general patient population” (FDA, 2011).

An updated version of the AUA and SUFU Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults document (Gormley, 2014) also addressed PTNS with an updated literature review and a change from “Option” to a recommendation, as follows:

> Clinicians may offer percutaneous tibial nerve stimulation (PTNS) as third-line treatment in a carefully selected patient population. *Recommendation* (Evidence strength – Grade C; Balance between benefits and risks/burdens uncertain).

This determination was based upon the following guideline discussion:

> The Panel interpreted these data to indicate that PTNS can benefit a carefully selected group of patients characterized by moderately severe baseline incontinence and frequency and willingness to comply with the PTNS protocol. Patients must also have the resources to make frequent office visits, in order to obtain treatment because treatment effects dissipate once treatment ceases. As a group, the PTNS studies constitute Grade C evidence because of the predominant observational designs, varying patient inclusion criteria, small sample sizes and short follow-up durations for most studies (Gormley, 2014).

Monga and colleagues (2012) reported a review of the clinical studies related to electrical stimulation for the treatment of lower urinary tract dysfunction. The authors found that median mean reductions in incontinence episodes and frequency were similar for SNS and PTNS. For PTNS, validated long-term follow-up data for PTNS are lacking. While there is a substantial amount of published research for SNS, it is not possible to define the appropriate role of SNS largely due to study design flaws (for example, changes in permanent implantation procedures) that inhibited intention to treat for the majority of the studies.

Burton and colleagues (2011) conducted a meta-analysis of the effectiveness of PTNS treatment for OAB. Their analysis found that there is evidence of significant improvement in OAB symptoms with PTNS that was comparable to the effect of antimuscarinics with PTNS having fewer side effects. The authors pointed out that the studies included in the review only considered short-term outcomes after initial treatment and that long-term outcome data and cost effectiveness are needed for PTNS to be considered as a practical treatment option.

In summary, PTNS is considered generally accepted as a treatment option for individuals with clinically significant urinary urge incontinence, urinary urgency/frequency, and non-obstructive urinary retention when symptoms are refractory to conservative treatment.

The evidence addressing the use of PTNS for other urinary conditions is limited. A recent AUA guideline addressing surgical treatment of female stress urinary incontinence did not provide any recommendations related to electrical stimulation for this condition (Kobashi, 2023). The authors state the following in their discussion:

> The Panel concludes that while laser or magnetic/ES therapy may provide some benefit compared to placebo it remains vital to counsel patients on the immaturity of the data. It appears current data does not suggest superiority of these new emerging technologies in comparison to established non-invasive therapies such as PFME.

This statement is supported, in part, by a Cochrane review by Stewart (2017). Their review included 51 studies (n=3781) comparing non-implanted electrical stimulation to other interventions or no intervention. The authors concluded the following:

> The current evidence base indicated that electrical stimulation is probably more effective than no active or sham treatment, but it is not possible to say whether ES is similar to PFMT or other active treatments in effectiveness or not. Overall, the quality of the evidence was too low to provide reliable results. Without sufficiently powered trials measuring clinically important outcomes, such as subjective assessment of urinary incontinence, we cannot draw robust conclusions about the overall effectiveness or cost-effectiveness of electrical stimulation for stress urinary incontinence in women.

PNTS for Fecal incontinence

PTNS has also been proposed for treatment of FI. The published literature consists of small observational studies quantified by measurements of FI episodes, ability to defer defecation, quality of life improvement and treatment success up to 14 months.

Hotouras and colleagues studied a prospective cohort of 88 women to identify factors that may predict PTNS for FI treatment response. The clinical outcomes measured were: (1) Cleveland Clinic incontinence scores, (2) deferment time and (3) weekly incontinence episodes. Outcomes were compared at baseline and following treatment using appropriate statistical tests. Clinical outcomes were correlated with the results of the anorectal physiology testing. The mean incontinence score improved from 12.2 ± 4.0 at baseline to 9.1 ± 4.6 following treatment ($p<0.0001$). Statistically significant improvements were also seen in the median deferment

time and median number of weekly incontinence episodes. Limitations of this study were that it was not randomized nor blinded which makes it difficult to draw conclusions regarding efficacy when compared to other available treatments.

Govaert and colleagues (2010) studied PTNS in 22 individuals with FI. Follow-up at 6 weeks showed that 13 participants had a greater than 50% decrease in incontinence episodes. Overall incontinence episodes fell from 19.6 ± 21.0 at baseline to 9.9 ± 15.5 ($p=0.082$) at 6 weeks and to 3.6 ± 4.8 ($p=0.029$) at 1 year.

In a prospective study over 14 months (median 9 months), Boyle and colleagues (2010) reported outcomes for PTNS therapy in 31 subjects with urge FI. Twenty-one (68%) participants improved following percutaneous tibial nerve stimulation and remain satisfied with the clinical response. Median fecal incontinence episodes per week declined from 4 (range, 0-30) to 0 (range, 0-27) ($p\leq0.0001$). The authors concluded that this preliminary study demonstrated that percutaneous tibial nerve stimulation is an effective and very well tolerated treatment for individuals with urge fecal incontinence with particular improvement in reducing fecal urgency.

Yu (2022) reported the results of a double-blind RCT involving 84 children with pelvic floor dysfunction-related constipation who were treated with PTNS plus pelvic floor exercises or sham PNTS plus pelvic floor exercises alone (n=42 in each group) for a total of 12 weeks. The PMTS device used was not described. A total of 75 subjects completed the trial (n=37 in the PNTS group vs. n=37 in the control group). At the end of treatment, 29 PTNS group subjects and 15 control group subjects had spontaneous bowl movements ≥ 3 per week from baseline. The authors reported the effectiveness rate was 69.0% in the PTNS group vs. 35.7% in the control group, with a net difference of 33.3% ($p<0.05$). Similarly, At the end of the 12-week follow-up, 26 PTNS group subjects and 15 control group subjects had spontaneous bowl movements ≥3 per week from baseline. The effectiveness rate was reported to be 61.9% in the PTNS group and 35.7% in the control group, with a net difference of 26.2% ($p<0.05$). Constipation symptoms recurred in 3 PTNS group subjects and in 1 control group subjects, resulting in recurrence rates of 10.34% and 6.67%, respectively. An analysis of secondary outcomes, including large diameter or scybalous stools, painful or hard bowel movements, excess volatile stool retention, and encopresis, were evaluated at both the end of treatment and at 12-week follow-up. All the statistical comparisons were significant and in favor of the PTNS group (all $p<0.05$). Remission of pelvic floor dysfunction occurred in 786% of subjects in the PTNS group and 38.1% of control group subjects (relative risk [RR], 2.063; $p<0.05$). Nine subjects with pelvic floor dysfunction remission (5 in the PTNS group and 4 in the control group) had no improvement in constipation symptoms. Adverse events included skin allergies, erythema, and blisters in 3 subjects (1 in the PTNS group and 2 in the control group) and foot numbness in 4 patients (2 in each group). All the symptoms were relieved after temporary withdrawal of the PTNS administration. The authors reported that PTNS plus pelvic floor exercises was “a safe and effective method in the treatment of childhood constipation, particularly in children with PFD or dyssynergic defecation.”. However, due to unclear specifics of the device used the utility and generalizability of these findings is unclear.

Implantable Tibial Nerve Stimulation

The Electroceutical eCoin Tibial Nerve Stimulator (Valencia Technologies Corporation, Valencia, CA) is a novel first-in-kind, battery-operated, peripheral neurostimulator device that provides intermittent electrical stimulation of the tibial nerve via a leadless nickel-sized and shaped device that is implanted subcutaneously near the ankle to treat urge urinary incontinence and is remotely controlled and adjusted by medical professionals. According to the FDA, approval of the premarket approval application (PMA) was announced on March 1, 2022 for the eCoin Peripheral Neurostimulator System for the following indication, subject to annual post-approval reports of safety and effectiveness:

> The eCoin® Peripheral Neurostimulator is intended to be used to treat urgency urinary incontinence in patients intolerant to, or having an inadequate response to, other more conservative treatments or who have undergone a successful trial of percutaneous tibial nerve stimulation (FDA, 2022).

FDA PMA approval was based on data from a single, prospective, multicenter, single-arm trial that evaluated the safety and effectiveness of the eCoin System in subjects with urgency urinary incontinence . Across 15 U.S. medical centers, 133 subjects were enrolled starting in August, 2018 with the final implant occurring in April, 2019. Procedures were performed primarily in office settings and all under local anesthetic. The study evaluated changes from baseline in urgency urinary incontinence episodes, as measured by voiding diaries and individual-reported outcomes through 48 weeks of eCoin therapy, (which is equivalent to 52 weeks from device implantation). Trial subjects who achieved at least a 50% improvement in the number of urgency urinary incontinence episodes, as measured in a 3-day voiding diary, were considered therapeutic successes (“responders”). The primary effectiveness endpoint was the proportion of responders after 48 weeks of therapy. The 3-day voiding diaries were self-reported and documented at least 3 days prior to the follow-up visit. The key secondary effectiveness endpoint was the proportion of subjects who achieved at least a 50% improvement in the number of urgency urinary incontinence episodes per 24 hours on a 3-day voiding diary (“responder rate”) after 24 weeks of therapy. The primary and secondary safety endpoints assessed device-related adverse events after implantation to 52 and 28 weeks respectively.

The primary efficacy analysis showed 68% (95% CI: 60%-76%) of subjects experienced at least a 50% reduction in urgency urinary incontinence episodes at 48 weeks post-activation; 16% of implanted subjects experienced device-related adverse events (AE) through 52 weeks post-implantation. Among the 133 implanted subjects, 52 weeks after implantation of the eCoin, a total of 23 subjects (17%) reported a device-related AE. For each time window (28 and 52 weeks from device implantation), 27 subjects (20%) reported at least one treatment-emergent AE related to the study device and/or procedure. Eighteen (18) subjects (14%) had serious AEs, 4 (3%) subjects reported serious AEs related to the device or procedure. At 48 weeks, in an exploratory analysis, no subjects reported severe stimulation pain (Rogers, 2021).

The durability of treatment effect was evaluated at 12 months post implantation in a prospective, single-arm, open-label study which included 46 subjects with refractory urgency urinary incontinence implanted with the eCoin device at 7 sites in the U.S. and New Zealand. Participants in this study were implanted with the eCoin in the lower leg over the tibial nerve and activated after 4 weeks. Bladder diary data and validated quality-of-life instruments, collected at 3, 6, and 12 months post-activation, were compared to baseline values. Responders were defined as those who had a ≥ 50% reduction in reported episodes of urgency urinary incontinence. At 12 months post implant, 65% of participants were considered responders with 26% achieving complete continence. The median number of urgency urinary incontinence episodes per day decreased from 4.2 at baseline to 1.7 at 12 months. Seventy percent of participants reported feeling "better", "much better", or "very much better" on the Likert 7-point maximum scale. One participant experienced a related serious AE (Gilling, 2021).

Similar to PTNS, implantable TNS is considered generally accepted as a treatment option for individuals with clinically significant urinary urge incontinence, urinary urgency/frequency, and non-obstructive urinary retention when symptoms are refractory to conservative treatment.

Definitions

Intrinsic sphincter deficiency (ISD): Stress incontinence caused by weakness of the urinary sphincter (a ring-like band of muscle fibers that constrict or close the natural opening to the bladder).

Neuromodulation: Stimulation of a nerve.

Overactive bladder syndrome (OAB): A general term used to describe urinary urgency, usually with urinary frequency and nocturia, with or without urgency/urinary incontinence. In most cases, the cause of the OAB is unknown. In some cases, it is associated with neurological conditions, such as multiple sclerosis or Parkinson's disease.

Sacral nerve: Any of five pairs of spinal nerves in the sacral region which innervate muscles and skin of the lower back, lower extremities, and perineum, and branches to the hypogastric and pelvic plexuses.

Sacral nerve stimulation: A permanent implantable device that stimulates the neural pathways controlling bladder function.

Stress urinary incontinence (SUI): The leakage of urine during physical activities that increase pressure on the bladder.

Tibial nerve: The medial terminal branch of the sciatic nerve. The tibial nerve fibers originate in lumbar and sacral spinal segments (L4 to S2). They supply motor and sensory innervation to parts of the calf and foot.

Urethra: The natural channel or tube through which urine passes from the bladder to outside of the body.

Urinary retention: The inability to completely empty the bladder of urine.

Urinary urge incontinence: Leakage of urine when there is a strong urge to void.

Urinary urgency-frequency: An uncontrollable urge to urinate resulting in very frequent, small volumes.

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Websites for Additional Information

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Axonics r-SNM® System
Electroceutical eCoin® Tibial Nerve Stimulator
Interstim™ Micro Sacral Neurostimulation System
Interstim Therapy System
NURO™ System
Percutaneous tibial nerve stimulation (PTNS)
Urgent PC Neuromodulation System
Sacral nerve stimulation for urinary incontinence
SacralStim system

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Revised	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised formatting of Clinical Indications section. Revised MN criteria for trial sacral nerve stimulators for urinary incontinence/urgency/frequency and retention to add new examples of conservative treatments. Revised permanent sacral nerve stimulators MN criteria for urinary urgency/frequency. Revised sacral nerve stimulation NMN statement. Added new MN criteria for percutaneous and implantable tibial nerve stimulation. Added new MN and NMN criteria for replacement or revision of percutaneous and Implantable tibial nerve stimulators. Revised percutaneous and implantable tibial nerve stimulation NMN statement. Updated Description, Discussion, References, Websites for Additional Information, and Index sections. Updated Coding section to include 01/01/2024 CPT changes; added 0786T, 0787T, 0816T, 0817T, 0818T, 0819T and revised descriptors for 64590, 0587T, 0588T; also removed 0589T, 0590T no longer applicable.
Revised	05/11/2023	MPTAC review. Added MN criteria for the temporary SNS for urinary and fecal conditions. Reformatted the MN criteria for permanent SNS for urinary and fecal conditions. Revised the title, description and Clinical Indications section IV for PTNS to include implantable devices. Updated the Discussion, Coding and References sections.
Revised	05/12/2022	MPTAC review. The requirement for a 12-month history of symptoms post vaginal delivery for SNS in FI was removed from criteria and clarified in a Note. Criteria for when replacements and revisions to SNS devices are MN were added. The Rationale and References sections were updated. Updated Coding section, added code 64585.
Reviewed	02/17/2022	MPTAC review. The Discussion and Reference sections were updated.
	12/29/2021	Updated Coding section with 01/01/2022 CPT descriptor change for 64581.
	10/01/2021	Updated Coding section with 10/01/2021 ICD-10-CM changes; added R35.89 replacing R35.8 deleted 09/30/2021.
Revised	02/11/2021	MPTAC review. The Clinical Indications and criteria were reformatted for clarification and statements about temporary SNS and trial periods were removed. The Discussion and References sections were updated.
Reviewed	11/05/2020	MPTAC review. References and Index sections were updated. Reformatted Coding section; added HCPCS codes C1820, C1883, L8685 and ICD-10-CM diagnosis R10.2.
	10/01/2020	Updated Coding section with 10/01/2020 ICD-10-CM changes; added K59.81-K59.89 replacing K59.8 deleted 09/30/2020.
Reviewed	11/07/2019	MPTAC review. The Discussion, Index and References sections were updated. Updated Coding section with 01/01/2020 CPT changes; added 0587T, 0588T, 0589T, 0590T.
New	01/24/2019	MPTAC review. Moved content of SURG.000117 Sacral Nerve Stimulation and Percutaneous Tibial Nerve Stimulation for Urinary and Fecal Incontinence; Urinary Retention to a new clinical utilization management guideline document with the same title. Removed acronyms from the Title and Clinical Indications section. The References section was updated.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.