Anthem BlueCross

Clinical UM Guideline

Subject: Sacral Nerve Stimulation and Percutaneous or Implantable Tibial Nerve Stimulation for Urinary and Fecal Incontinence; Urinary Retention

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Description

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

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.

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: Please see the following related documents for additional information:

- 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 botulinum toxin is not addressed in this document.

Clinical Indications

Medically Necessary:

I. Sacral nerve stimulation: Urinary urge incontinence, urgency/frequency, and retention

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

A. Any of the following are present 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, exercises, medication, or for non-obstructive urinary retention: intermittent catheterizations) for at least a sufficient duration to fully assess treatment effect.*****

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

A. The individual has met criteria above for evaluation for a 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;
   2. For urinary urgency/frequency: At least 50% reduction in one of the following: number of voids daily, volume per void or frequency per void;
   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: Fecal Incontinence

Placement of a trial or temporary sacral nerve stimulator is considered **medically necessary** for individuals when the criteria A **and** B are met:

A. Treatment is for fecal incontinence; **and**
B. **BOTH** of 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 had a successful trial of the temporary sacral nerve stimulator defined as:
    1. The individual has met the criteria above for evaluation for a temporary sacral nerve stimulator; **and**
    2. Temporary sacral nerve stimulation shows 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. Sacral nerve stimulation: Replacements and Revisions

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:

Sacral nerve stimulator therapy is considered **not medically necessary** for urinary urge incontinence, urgency/frequency, and retention for indications other than the medically necessary indications listed above, including, but not limited to, the following:

A. Urge incontinence due to a neurologic condition (for example, detrusor hyperreflexia);
B. Stress incontinence and other types of chronic voiding dysfunction due to neurologic conditions (for example, spinal cord injury, diabetic neuropathy, multiple sclerosis);
C. Chronic pelvic pain.

Sacral nerve stimulation is considered **not medically necessary** for fecal incontinence that may be related to:

A. Rectal surgery for conditions other than cancer, performed within the past 12 months; **or**
B. Rectal surgery for cancer performed within the past 24 months; **or**
C. Anorectal malformation (for example, congenital anorectal malformation); **or**
D. Visible sequelae of pelvic radiation; **or**
E. Active anal abscesses and fistulae; **or**
F. Chronic inflammatory bowel disease; **or**
G. Peripheral neuropathy; **or**
H. Complete spinal cord injury (no motor or sensory function at sacral segments S4-S5); **or**
I. Constipation.

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

Not Medically Necessary:

Percutaneous or implantable tibial nerve stimulation is considered **not medically necessary** for all indications, including but not limited to:

A. All indications dealing with urinary dysfunction, including but not limited to, treatment of overactive bladder symptoms, such as urinary urgency, urinary frequency and urge incontinence, stress incontinence, non-obstructive urinary retention and interstitial cystitis;
B. All indications dealing with fecal dysfunction, such as incontinence, constipation, inflammatory bowel disease, and anal sphincter dysfunction.

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)
	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 or gastric neurostimulator pulse generator or receiver, direct or inductive coupling [*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 including, but not limited to the following:

ICD-10 Diagnosis	
F45.8	Other somatoform disorders [psychogenic constipation]
F98.0-F98.1	Enuresis/encopresis not due to a substance or known physiological condition
K50.00-K50.919	Crohn’s disease (regional enteritis)
K51.00-K51.919	Ulcerative colitis
K52.0	Gastroenteritis and colitis due to radiation
K58.0-K58.9	Irritable bowel syndrome
K59.00-K59.09	Constipation
K59.1	Functional diarrhea
K59.2	Neurogenic bowel
K59.81-K59.89	Other specified functional intestinal disorders (atony of colon)
K60.0-K60.5	Fissure and fistula of anal and rectal regions

K61.0	Anal abscess
K61.2	Anorectal abscess
K63.0-K63.9	Other diseases of intestine
K91.1	Postgastric surgery syndromes
N13.8-N13.9	Other/unspecified obstructive and reflux uropathy
N30.00-N30.91	Cystitis
N31.0-N31.9	Neuromuscular dysfunction of bladder, not elsewhere classified
N32.0	Bladder-neck obstruction
N36.41-N36.44	Urethral functional and muscular disorders
N36.8	Other specified disorders of urethra
N39.3	Stress incontinence (female) (male)
R10.2	Pelvic and perineal pain
R32	Unspecified urinary incontinence
R39.81	Functional urinary incontinence

Percutaneous or Implantable Tibial Nerve Stimulation

When services are Not Medically Necessary:

For the following procedure codes, or when the code describes a procedure designated in the Clinical Indications section as not medically necessary.

CPT	
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming
0587T	Percutaneous implantation or replacement of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve
0588T	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve
0589T	Electronic analysis with simple programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, posterior tibial nerve, 1-3 parameters
0590T	Electronic analysis with complex programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, posterior tibial nerve, 4 or more parameters
	For the following CPT code **when specified as a leadless implantable tibial neurostimulator**:
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling [*when specified as a leadless tibial neurostimulator (for example eCoin® Peripheral Neurostimulator***)**]*
ICD-10 Diagnosis	
	All diagnoses

Discussion/General Information

A sacral nerve stimulator (SNS) is a device that is surgically implanted (different from pelvic floor stimulation) to treat urinary or fecal incontinence. It is standard of care to conduct a “test phase” as part of the SNS insertion procedure. A temporary percutaneous nerve evaluation (PNE) lead is usually placed in the outpatient clinical setting, although some clinicians may insert a permanent lead wire in a surgical setting that connects to a temporary stimulation device. Prior to implantation of a temporary SNS device, a trial period of sacral nerve neuromodulation, with either percutaneous nerve stimulation or a temporarily implanted lead, is performed, in order 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 individual response and candidacy for the permanent device. A temporary SNS device is then implanted under local anesthesia and left in place for several days. This temporary device is connected to a portable external stimulator, which is carried in the pocket or attached to a belt. The individual can then keep track of voiding symptoms while the temporary device is functioning. The results of this test phase are used to determine whether individuals are appropriate candidates for the permanent SNS device. The rate of adverse events from SNS is reported in the available trials as significantly high,

although most events are minor and resolve with treatment or device revision. However, reported adverse events have included post-implant pain, infection, adverse changes in bowel function, lead migration, and electric shock sensation.

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.

Sacral Nerve Stimulation (Interstim® Medtronic Inc., Minneapolis, MN)

The InterStim™ System for Urinary Control (Medtronic, Inc., Minneapolis, MN), was investigated in a large multicenter, randomized clinical trial 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 InterStim Neurostimulator was originally cleared by the Food and Drug Administration (FDA) in 1998 for urinary incontinence and received additional labeled approval for urinary retention in 1999. Additional updated models have obtained FDA clearances; the most recent is the Medtronic InterStim Micro rechargeable sacral neuromodulation (SNM) system 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).

Urinary incontinence

Brazzelli and colleagues (2006) conducted a systematic review for the efficacy and safety of SNS for urge incontinence. Four randomized controlled trials and 30 case series were identified. The randomized controlled trials, involving approximately 120 subjects, showed that about 80% achieved continence or greater than 50% improvement in their main incontinence symptoms after SNS, compared with about 3% of controls who received conservative treatments while waiting for an implant. While the case series were larger, they were methodologically less reliable. The case series showed similar results with 67% of individuals becoming dry or achieving a greater than 50% improvement in symptoms after implantation. Increased urine continence was reported to last 3 to 5 years after implantation. Adverse events were documented in 27 studies. The most common complications were pain at the implant or lead site in 25% of individuals, lead related problems such as lead migration in 16%, replacement and repositioning of the implanted pulse generator in 15%, and wound problems in 7%. Nine percent of the participants required removal of the electrodes. The authors concluded that the evidence supports the efficacy of the SNS device for decreasing incontinence. Device revisions have been shown to reduce the adverse effects.

Herbison and colleague (2009) reported on eight randomized studies that evaluated implants which provided continuous stimulation. Although there were adverse effects and methodological problems with the studies, the authors concluded that continuous stimulation offers benefits for, “Carefully selected people with overactive bladder syndrome and for those with urinary retention but no structural obstruction.” The authors also advocated that the effectiveness of implants should be tested against other interventions, particularly in people with an overactive bladder.

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).

The *neurogenic* bladder is not addressed in this document (see CG-SURG-08 Sacral Nerve Stimulation as a Treatment of Neurogenic Bladder Secondary to Spinal Cord Injury). The term, neurogenic bladder, is defined by the AUA/SUFU in another document, the *Guideline on Adult Neurogenic Lower Urinary Tract Dysfunction,* as follows:

> The term neurogenic lower urinary tract dysfunction (NLUTD) refers to abnormal function of either the bladder, bladder neck, and/or its sphincters related to a neurologic disorder. Prior terminology commonly used "neurogenic bladder" to describe this condition. With the understanding that this is not just an issue confined to the bladder, NLUTD is now the preferred way to describe the various voiding issues seen in patients with a neurologic disorder (Ginsberg, 2021).

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 is subject to periodic post-approval safety reports to be submitted to the FDA.

According to the FDA Summary of Safety and Effectiveness Data (SSED):

> The components of the Axonics SNM System used for urinary control are identical to those of the system of the same name used for bowel control (approved under P190006). Many of the Axonics system components are also similar to those used in the Medtronic InterStim Therapy System (FDA, 2019).

Fecal incontinence

In the past, SNS for fecal incontinence (FI) has been reported in small case series suggesting potential benefit from this therapy (Ganio, 2001; Kenefick, 2002; Rosen, 2001).

The Food and Drug Administration (FDA) cleared the Interstim Therapy (Medtronic, Inc., O'Fallon, IL) device for the application of FI 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 acknowledged that 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 approved for sale in the United States, Europe, Canada and Australia. 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).

Leroi and colleagues (2005) addressed SNS treatment of FI for a possible placebo effect in a randomized, double-blind, crossover study. Thirty-four participants underwent sacral nerve stimulation for fecal incontinence. After implantation, 27 of the 34 participants were randomized in a double-blind crossover design to stimulation ON or OFF for 1-month periods. While still blinded, the participants chose the period of stimulation (ON or OFF) that they had preferred. The mode of stimulation corresponding to the selected period was continued for 3 months (final period). Outcome measures were frequency of fecal incontinence and urgency episodes, delay in postponing defecation, score severity, feeling of improvement, preference for ON or OFF, quality of life, and manometric measurements. Twenty-four participants completed the 3-month study. The results showed that the frequency of fecal incontinence episodes was significantly reduced during the ON versus the OFF period. In the final period of the study, the frequency of fecal incontinence episodes decreased significantly in those with the stimulator ON. The ability to postpone defecation, the score for

symptom severity, and the quality of life as well as anal sphincter function significantly improved. The results of this study indicate that the clinical benefit of sacral nerve stimulation was not due to placebo.

Tjandra and colleagues (2008) studied SNS for FI in 53 individuals randomized to SNS and 60 individuals randomized to the best supportive therapy, consisting of pelvic floor exercises with biofeedback, bulking agents, and dietary management. At baseline, the SNS group had an average of 9.5 incontinent episodes per week, and the controls had 9.2. Both groups had an average of 3.3 days per week with incontinence. At 12-month follow-up, episodes had decreased to 1 day per week with 3.1 episodes in the SNS group, but had not changed in the control group (mean 3.1 days per week with 9.4 episodes). Complete continence was achieved in 22 of the 53 SNS group (42%) and 13 (24%) improved by 75% to 99%.

Matzel and colleagues (2008) reported long-term outcomes on 9 individuals who were treated with SNS implantation for severe FI between 1994 and 1999. Continued efficacy averaged 10 years (range 7-14 years). Complete continence was achieved in 5 participants and 3 had less than 10% incontinent episodes. Complications occurred in 5 of the original 12 and were therapy-related. After 7 years, device battery life was exhausted in 8 participants and required replacement.

Wexner and colleagues (2010) reported results from a prospective, multicenter study of SNS for FI. 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.

While the literature supports SNS for FI, 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 (Urgent® PC Neuromodulation System Uroplasty, Inc., Minnetonka, MN)

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.

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 ($p \leq 0.001$). 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.

In 2014, Blue Cross and Blue Shield Association TEC Assessment addressed percutaneous tibial nerve stimulation for the treatment of voiding dysfunction. Their findings were summarized as follows:

> The body of evidence suggests that PTNS is efficacious versus a placebo sham procedure in relieving symptoms of OAB syndrome and urinary voiding dysfunction in the initial treatment phase. Although weak, clinical trial evidence further supports a conclusion that PTNS is at minimum as effective as several standard comparators. The technique appears to be safe when applied as reported and has not been associated with significant harms (TEC, 2014).

This 2014 TEC Assessment found that PTNS meets TEC criteria for the treatment of voiding dysfunction, based on short-term efficacy data. However, questions remain regarding the lack of controlled evidence on maintenance PTNS and additional concerns about whether short-term efficacy is maintained over periods longer than 36 months.

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).

The updated AUA and SUFU Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults (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.

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.

Implantable Tibial Nerve Stimulation (eCoin® Tibial Nerve Stimulator (Valencia Technologies Corporation, Valencia, CA)

The Electroceutical eCoin Tibial Nerve Stimulator (Valencia Technologies Corporation, Valencia, CA) is a new 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 UI 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 (UUI). 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 UUI 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 UUI 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 UUI 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 UUI 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 UUI 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 UUI. At 12 months post implant, 65% of participants were considered responders with 26% achieving complete continence. The median number of UUI 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).

The evidence, to date, regarding the safety and efficacy of the eCoin device consists of limited short-term trials. Additional evidence is needed in larger well-designed trials with additional data regarding the durability of therapeutic effect and adverse event rates.

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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Index

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	05/11/2023	Medical Policy & Technology Assessment Committee (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.