

Clinical UM Guideline

Subject: Tibial Nerve Stimulation
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Description

This document addresses tibial nerve stimulation (TNS) in individuals with urinary retention, chronic urinary incontinence and chronic fecal incontinence.

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

- CG-MED-97 Biofeedback and Neurofeedback
- DME.00011 Electrical Stimulation as a Treatment for Pain and Other Conditions: Surface and Percutaneous Devices
- 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:

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.*

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* **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 following 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.

Transcutaneous tibial nerve stimulation, including tibial nerve neuromodulation, is considered **not medically necessary** for all indications.

Coding

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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.

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.

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Tibial Nerve Stimulation

When services are also Not Medically Necessary:

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

CPT

0988T	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 and subfascial
0989T	Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subcutaneous and subfascial

HCPCS

A4545	Supplies and accessories for external tibial nerve stimulator (e.g., socks, gel pads, electrodes, etc.), needed for one month [e.g., supplies for Vivally and ZIDA systems]
E0736	Transcutaneous tibial nerve stimulator [e.g., ZIDA Wearable Neuromodulation control unit, Vivally System with hardware control unit]
E0737	Transcutaneous tibial nerve stimulator, controlled by phone application [e.g., Vivally System, smartphone]

ICD-10 Diagnosis

All diagnoses

Discussion/General Information

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 Sacral Nerve Stimulation (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.

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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 participants. 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 participants 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 (OAB) syndrome. Participants had to have symptoms of OAB with at least 8 voids per 24 hours; the mean daily voids for those entering the study were 12.3. The primary outcome was the 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 participants completing 6 and 12 months of therapy, respectively. Participants 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 participant 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 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%)

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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.

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 participant 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 participants 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's Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults document guideline (Gormley, 2014) also addressed PTNS with an updated literature review and a change from "Option" to a recommendation, as follows:

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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.

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Tibial Nerve Stimulation

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.

In 2024, the AUA and SUFU issued an updated guideline on the diagnosis and treatment of OAB. According to their recommendation, individuals with OAB, “who have an inadequate response to, or have experienced intolerable side effects from, pharmacotherapy or behavioral therapy, clinicians should offer sacral neuromodulation, percutaneous tibial nerve stimulation, and/or intradetrusor botulinum toxin injection. (Moderate Recommendation; Evidence Level: Grade A)”

PTNS 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 participants 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) ($p \leq 0.0001$). 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.

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In the 2017 AGA clinical practice for fecal incontinence and defactory disorders they stated, “Until further evidence is available, percutaneous tibial nerve stimulation should not be used for managing FI in clinical practice.”

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 participants completed the trial (n=37 in the PNTS group vs. n=37 in the control group). At the end of treatment, 29 PTNS group participants and 15 control group participants had spontaneous bowel 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 participants and 15 control group participants had spontaneous bowel 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 participants and in 1 control group participants, 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 78.6% of participants in the PTNS group and 38.1% of control group participants (relative risk [RR], 2.063; $p<0.05$). Nine participants 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 participants (1 in the PTNS group and 2 in the control group) and foot numbness in 4 participants (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.

Luo and colleagues (2024) conducted a meta-analysis including four RCTs for a total of 439 individuals, 300 of which were randomized to the PTNS group and 100 to a sham control group. The meta-analysis showed that PTNS significantly reduced weekly FI episodes (Mean difference [MD]: -1.6; 95% confidence interval [CI], -2.94 to -0.26; $p=0.02$) and a higher proportion of individuals reported over a 50% reduction in FI episodes (Relative risk [RR]: 0.73; 95% CI, 0.57–0.94; $p=0.02$). No significant differences were observed in FI QOL and St Mark’s incontinence scores (MD: -2.41; 95% CI, -5.1 to 0.27; $p=0.08$). No severe adverse events related to PTNS were reported.

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

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Tibial Nerve Stimulation

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 premarket approval was based on data from a single, prospective, multicenter, single-arm trial that evaluated the safety and effectiveness of the eCoin System in participants with urgency urinary incontinence (Rogers, 2021). Across 15 U.S. medical centers, 133 participants 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 participants 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 participants 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 participants experienced at least a 50% reduction in urgency urinary incontinence episodes at 48 weeks post-activation; 16% of implanted participants experienced device-related adverse events (AE) through 52 weeks post-implantation. Among the 133 implanted participants, 52 weeks after implantation of the eCoin, a total of 23 participants (17%) reported a device-related AE. For each time window (28 and 52 weeks from device implantation), 27 participants (20%) reported at least one treatment-emergent AE related to the study device and/or procedure. Eighteen (18) participants (14%) had serious AEs, 4 (3%) participants reported serious AEs related to the device or procedure. At 48 weeks, in an exploratory analysis, no participants reported severe stimulation pain.

The durability of treatment effect was evaluated at 12 months post implantation in a prospective, single-arm, open-label study which included 46 participants 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 $\geq 50\%$ 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).

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Tibial Nerve Stimulation

Lucente (2024) published the results of the extension phase of the Rogers (2021) study, following 72 participants to their 96-week visit. At least a 50% reduction in UII episodes was reported in 78% of participants. In addition, 48% (95% CI, 36%-60%) of participants experienced at least a 75% reduction in urinary urge incontinence episodes, and 22% were reported as dry in their 3-day diary. At baseline, the mean urinary urge incontinence episode was 4.32 per day, which decreased by 2.97 per day on the 96th week post-activation. Similarly, urinary voids per day decreased from 13.06 to 1.89 by 96 weeks. While the use of supplemental medications was allowed in the extension phase of the study, only 8.7% of participants chose to use them. The authors reported an overall responder rate of 84%. In this extension study between 48 and 96 weeks post-implantation, no device- or procedure-related serious adverse events were reported. Two additional participants reported device- or procedure-related non-serious adverse events, including extremity pain, and wound dehiscence. The authors concluded that the results demonstrated consistent continuing effectiveness and safety.

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.

Transcutaneous Tibial Nerve Stimulation (TTNS) for OAB

TTNS has been proposed as an alternative to PTNS and implantable TNS, based on the wide availability of standard TNS devices and the convenience of at-home therapy.

Several RCTs have been published comparing TTNS to sham therapy. Some of these trials have reported no significant differences between groups with regard to frequency of incontinence, urodynamic measures, symptom severity, QOL and other factors (Boudaoud, 2015; Shah, 2024). Other studies reported significant improvement in the TTNS group for similar measures (Araujo, 2020; McClurg, 2022; Patidar, 2015; Stampas, 2024). Additionally, these studies involve a wide range of indications, including OAB due to Parkinson's Disease, neurogenic bladder due to spinal cord injury, and pediatric OAB. Due to the heterogeneity in the reported findings and methodologies of these studies, the generalizability of their findings is unclear.

The use of TTNS has been compared to the standard of care, PTNS, in several trials for idiopathic overactive bladder with reported results similar to those reported in the sham comparison trials. One study reported no significant differences between groups, concluding non-inferiority (Ramírez-García, 2019). However, this study was not appropriately powered to make that conclusion. Another study reported differences between groups with regard to level of comfort, treatment satisfaction, and preparation time in favor of TTNS, but no differences between groups with regard to incontinence episodes or severity were reported (Sonmez, 2022). The third trial reported more favorable results in the PTNS group compared to the TTNS group with regard to reduction in clinical symptoms and QOL measures. The authors concluded that while both methods result in significant improvements from baseline, PTNS provided significantly better results (Zonić-Imamović, 2021). There was a high degree of variability in these trials with regard to treatment frequency and duration. As with the sham-controlled trials previously discussed, due to the heterogeneity in the reported findings and methodologies of these studies, the generalizability of their findings is unclear.

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There are currently no available studies comparing the use of TTNS to implantable TNS.

The optimal stimulation threshold for TTNS is unclear. To date, these factors have only been investigated in a limited number of trials, with the majority of trials having participants increase stimulation intensity to either the motor or sensory threshold and then dial back stimulation to a comfortable level. Teixeira Alve (2020) reported the results of a blind RCT of participants with OAB using TTNS twice a week for 4 weeks with the device set to the motor threshold or the sensory threshold. The authors reportedly found no significant differences between stimulation groups of urinary habit measures reported in bladder diaries at 5 weeks. However, the short follow-up time and treatment frequency limit the utility of these results.

No high-quality studies have been published evaluating the optimal treatment frequency or duration for TTNS.

While TTNS treatment is most often applied with standard TNS devices, several specialized devices have been developed and are available on the market, including The Zida[®] Control Sock and the Vivally[®] system.

The Zida Control Sock is a non-invasive wearable neuromodulation system intended to provide tibial nerve stimulation. The device received FDA clearance on March 19, 2021 for the treatment of OAB and associated symptoms including urinary frequency, urge urinary incontinence, and urinary urgency. The device is a sock that incorporates TNS electrodes and a detachable battery-operated control unit. The current is in the form of a monophasic square wave and is user-adjustable between 0.0 and 156 mA at 20 Hz.

Cava (2022) reported on the results of a prospective, blinded, randomized, controlled trial involving 40 participants with OAB treated with either an activated Zida sock (n=21) or sham treatment with a nonactive Zida sock (n=9). Participants received training in the use of the device and then self-administered treatment once weekly for 30 minutes for 12 weeks. All participants had a score of greater than 60 on the International Consultation on Incontinence Questionnaire Male Lower Urinary Tract Symptoms Module (ICIQ-MLUTS) or International Consultation on Incontinence Questionnaire Female Lower Urinary Tract Symptoms Module (ICIQ-FLUTS), and had a 2-week washout period of any concomitant anticholinergic or beta-agonist medications. Compliance was self-reported via weekly telephone interview. All participants were advised that lack of a motor or sensory response during treatment did not indicate a lack of treatment effect. The Zida group reported a larger decrease in 24-hour urinary frequency compared to the control group (p<0.06). Overall, 25% of the Zida group had at least a 30% reduction in 24-hour urinary frequency compared to 0% in the control group (p=0.048). For urgency voids, the success rate in the Zida group was 80% (n=16/20), which was reported as significantly larger than the control group at 39% (n=7/18, p=0.02). The incontinence success rate in the Zida group was 75%, compared to 33% in the control group (p=0.04). Excluding participants that had no incontinence episodes at both baseline and week 12, the treatment incontinence success rates were 72% (n=13/18) in the Zida group and 25% (n=4/16) in the control group (p=0.02). The authors concluded that the primary endpoint, clinical treatment success defined as at least a 50% reduction in urgency voids with or without incontinence or at least a 30% reduction in 24-hour frequency voids from baseline to week 12 of the study was met. The secondary endpoint, change in QOL from baseline to week 12, was also met, with a significant improvement in QOL total score from baseline to week 12 in the Zida group compared to the control group (p<0.001). Overall, 5 adverse events were reported, including 2 cases of urinary tract infections (UTI) in the Zida group. Neither was deemed to be related to the intervention. Two additional

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participants, also in the Zida group, reported single episodes of foot pain. The episodes were either during or immediately after treatment and resolved within 30 minutes of treatment cessation. The authors did not comment on whether or not the episodes were related to the Zida device. The final event was in one participant in the control group who dropped out of the study due to suspected COVID-19 infection.

The Vivaly system is another wearable non-invasive neuromodulation system intended to provide tibial nerve stimulation. The device received FDA clearance on April 3, 2023 for the treatment of urge urinary incontinence and urinary urgency. It is the first such device that incorporates an electromyographic (EMG) evaluation function, allowing closed-loop wearable therapy for bladder control. The EMG function is intended to confirm activation of the tibial nerve to monitor treatment response. The device is purported to adjust neuromodulation energy parameters during therapy to ensure optimal therapeutic output.

The use of the Vivaly device was investigated for the treatment of OAB in a case series study involving 96 participants (Goudelocke, 2023) who completed bladder diaries and QOL instruments. Inclusion criteria were adults diagnosed or having symptoms of OAB for ≥ 3 months, with an average of ≥ 10 daily voids on a 3-day bladder diary, and a detectable EMG signal. Participants were asked to use the device for one-three 30-minute sessions per week for 12 weeks, and had in-person or remote visits at 1, 4, 8, and 12 weeks. At the end of the 12-week period, participants were given the opportunity to continue treatment to continue data collection with a change in treatment frequency to twice per month. The authors reported significant reductions in voiding events in 94.7% of participants, stating that urinary frequency showed a mean reduction of 2.84 ± 2.4 ($p < 0.0001$) from baseline. Incontinence episodes in 80.8% of participants were reduced by 1.91 ± 3.1 ($p < 0.0001$), and urgency episodes in 78.7% of participants decreased by 3.09 ± 3.9 ($p < 0.0001$). A total of 25.8% of participants returned to ≤ 8 voids/day, 23.7% reported no daily leaks, and 25.7% reported no daily urgency episodes at 12 weeks. In evaluating QOL, changes in the domains of coping, concern/worry, sleep, and social interaction all exceeded the Minimal Clinically Important Difference (MCID) of 10 points, with most domains at least twice the MCID. A total of 50 participants continued past the 12-week time point, with 47 (94%) and 39 (78%) completing an additional 6 and 12 months of treatment. The 6-month mean reduction in urinary frequency was 2.67 ± 2.5 ($p < 0.0001$), reduction in episodes of urge urinary incontinence was 2.13 ± 3.0 ($p < 0.0001$), and reduction in urge incontinence episodes was 3.97 ± 5.2 ($p < 0.0001$). At 12 months the mean reduction in urinary frequency was 1.85 ± 2.8 ($p < 0.0001$), reduction in episodes of urge urinary incontinence was 1.29 ± 3.9 ($p = 0.0556$), and reduction in urge incontinence episodes was 2.84 ± 4.9 ($p = 0.0040$). The authors noted that the durability of benefit was demonstrated in the long-term follow-up despite a reduction in treatment frequency.

At this time, use of TTNS for OAB, urinary urge incontinence, and urinary retention is not in accordance with generally accepted standards of medical practice, and no authoritative specialty medical societies recommend such use.

TTNS for Fecal incontinence

The use of TTNS for the treatment of fecal incontinence has been investigated, but the results of these trials have been mixed. While some methodologically limited non-comparative studies have shown some benefit from TTNS (Dedimandi, 2018; Jiménez-Toscano, 2012), several well-designed RCTs have shown no benefit compared to sham

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therapy (Leroi, 2012) or superiority of PTNS over TTNS (George, 2018). Given this equivocal evidence, the use of TTNS for the treatment of fecal incontinence has not been recognized as a generally accepted treatment method and no authoritative specialty medical societies recommend such use.

TTNS for Other Indications

TTNS has been proposed for the treatment of a wide range of other indications, including bladder pain syndrome (Alkis, 2022), chronic anal fissure (Youssef, 2015), chronic prostatitis and chronic pelvic pain syndrome (Sevim, 2022), dysmenorrhea (Correyero-León, 2024a and 2024b), and sexual function (Giannopapas, 2024). To date the use of TTNS for such indications has not been accepted in general practice.

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.

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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Electroceutical eCoin® Tibial Nerve Stimulator

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Tibial Nerve Stimulation

NURO™ System
 Percutaneous tibial nerve stimulation (PTNS)
 Urgent PC Neuromodulation 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
	12/18/2025	Updated Coding section with 01/01/2026 CPT changes, added 0988T, 0989T.
New	02/20/2025	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development. Moved content for tibial nerve stimulation from CG-SURG-95 Sacral Nerve Stimulation and Percutaneous or Implantable Tibial Nerve Stimulation for Urinary and Fecal Incontinence, Urinary Retention to new clinical utilization management guideline document. Added NMN position for transcutaneous tibial nerve stimulation and added codes A4545, E0736, E0737.

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