



## Posterior Tibial Nerve Stimulation Clinical Coverage Criteria

### Overview

Posterior (or percutaneous) tibial nerve stimulation (PTNS), also referred to as posterior tibial (or percutaneous) neuromodulation, is a minimally invasive, office-based treatment for patients with overactive bladder (OAB). OAB is a chronic condition associated with complaints (symptoms) of urinary urgency, with or without urge urinary incontinence, usually with increased daytime frequency and nocturia.

Normal urinary control is dependent upon competent neural pathways and coordination among the central and peripheral nervous systems. Disrupted nerve signals can lead to OAB. Neuromodulation incorporates electrical stimulation that targets specific neural tissue. To modulate urinary dysfunction, the signals must be delivered to the nerve tissue affecting bladder activity. The tibial nerve is a mixed nerve containing L4-S3 fibers (the same spinal segments that provide innervation to the bladder and pelvic floor).

The device used to deliver PTNS is a combination of a small gauge needle-electrode, a surface grounding electrode, lead wires, and a low-voltage generator. The needle-electrode is inserted percutaneously into the tibial nerve approximately two inches cephalad to the medial malleolus. After the lead wire and surface electrode are attached, the device is turned on and amplitude is slowly increased. The stimulator is left in place with the patient controlling the power for 30 minutes. Treatments are usually given once weekly for 12 consecutive weeks, but treatment variations include an accelerated protocol (3 times per week for 4 weeks). Following the initial treatment phase, maintenance treatment is continued indefinitely. The protocol for maintenance treatment is tailored to each individual patient; typically one treatment is required every 2 to 3 weeks.

Because OAB is a chronic condition it is important to evaluate PTNS over the long term. Efficacy of PTNS during the initial treatment phase does not automatically imply efficacy or improved outcomes during the maintenance phase. Therefore when evaluating PTNS as a treatment for OAB, it must be shown that PTNS is effective in reducing symptoms during the 12-week treatment phase and that response is durable. PTNS has little practical utility unless the treatment effect can be maintained over long periods. This will require demonstration in high-quality trials that show that the maintenance phase of the treatment is effective.

### Policy

This Policy applies to the following Fallon Health products:

- Fallon Medicare Plus, Fallon Medicare Plus Central (Medicare Advantage)
- MassHealth ACO
- NaviCare HMO SNP (Dual Eligible Medicare Advantage and MassHealth)
- NaviCare SCO (MassHealth-only)
- PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
- Community Care (Commercial/Exchange)

Effective for dates of service on or after 09/01/2024, prior authorization is not required for posterior tibial nerve stimulation (CPT code 64566).

## Fallon Health Clinical Coverage Criteria

Fallon Health Clinical Coverage Criteria apply to Community Care and MassHealth ACO members.

An initial course of posterior tibial nerve stimulation (PTNS) is considered medically necessary for the treatment of symptomatic non-neurogenic overactive bladder (OAB) when all of the following criteria are met:

1. The plan member been evaluated by a specialist, usually a urologist or urogynecologist, and the specialist has determined that the patient is a candidate for PTNS.
2. The medical record documents the following:
  - a. The plan member has been compliant with and failed a trial of symptom-appropriate behavioral therapy (e.g., bladder training, bladder control strategies, pelvic floor muscle training, fluid management) of sufficient length to evaluate potential efficacy, and
  - b. The plan member been compliant with and has failed a trial of at least one anti-muscarinic medication administered for 4 to 8 weeks.
3. The plan member has documented a willingness to attend weekly in-office treatment sessions and to keep a bladder/voiding diary to monitor bladder symptoms and track the efficacy of the intervention.

An initial course of PTNS consists of one 30-minute session per week for 12 weeks.

Monthly maintenance treatments will be authorized for those plan members who achieve a >50% decrease in OAB symptoms (e.g., decreased urinary urgency, decreased urge incontinence, decreased frequency and/or nocturia) with the initial 12-week treatment.

If the member fails achieve a >50% decrease in OAB symptoms after an initial 12-week course, continued treatment is not medical necessity.

Failure of an anti-muscarinic medication may include lack of efficacy and/or inability to tolerate adverse drug effects.

Behavioral therapies may be combined with pharmacologic management.

This is the minimum definition of a refractory patient. Individual clinicians and patients may decide that it is in the best interests of the patient to persevere with behavioral and/or pharmacologic therapy for longer periods, to combine behavioral and pharmacologic therapies to achieve better efficacy, or to try alternate medications before judging that a patient is refractory.

## Medicare Variation

Medicare statutes and regulations do not have coverage criteria for posterior tibial nerve stimulation. Medicare does not have an NCD for posterior tibial nerve stimulation. National Government Services, Inc., the Part A and B Medicare Administrative Contractor with jurisdiction in the Plan's service area has an LCD for Posterior Tibial Nerve Stimulation (L33396) (Medicare Coverage Database search 09/22/2025). Coverage criteria for posterior tibial nerve stimulation are fully established by Medicare; therefore, the Plan's coverage criteria are not applicable.

[Link: National Government Services, Inc. LCD Posterior Tibial Nerve Stimulation for Voiding Dysfunction \(L33396\)](#)

## MassHealth Variation

MassHealth does not have Guidelines for Medical Necessity Determination for posterior tibial nerve stimulation (MassHealth website search 09/22/2025), therefore, the Plan's coverage criteria are applicable.

## Exclusions

- Any other use of posterior tibial nerve stimulation including but not limited to fecal incontinence and neurogenic bladder dysfunction.

- Transcutaneous tibial nerve stimulation, for example ZIDA Wearable Neuromodulation Unit (Zida, LLC), and Vivaly System Wearable Non-Invasive Neuromodulation System and Mobile Application (Avation Medical, Inc.) are considered experimental/investigational and not medically necessary. Accordingly, the following HCPCS codes are considered experimental/investigational and not medically necessary:
  - HCPCS code E0736 (Transcutaneous tibial nerve stimulator)
  - HCPCS code E0737 (Transcutaneous tibial nerve stimulator, controlled by phone application) is considered experimental/investigational and not medically necessary.
  - HCPCS code A4545 (Supplies and accessories for external tibial nerve stimulator (e.g., socks, gel pads, electrodes, etc.), needed for one month.
  - Note: HCPCS code E0731, (Form fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patient's skin by layers of fabric)) is not covered when used to report ZIDA Wearable Neuromodulation control sock.
- Implanted posterior tibial nerve stimulation devices, for example Protect PNS device (Uro Medical Corporation), are considered experimental/investigational and not medically necessary. Note: On October 19, 2016, CMS approved Medicare coverage for the Category B IDE study associated with the Protect PNS device (G15078). Category B IDE studies are covered by Fallon Health for Medicare Advantage plan members. The CPT codes associated with the Protect PNS device are 0587T, 0588T, 0589T and 0590T. See Coding section below.

## Summary of Evidence

### Transcutaneous Tibial Nerve Stimulation

Transcutaneous tibial nerve stimulation (TTNS) is noninvasive method of stimulating the posterior tibial nerve (PTNS). The primary difference between TTNS and PTNS is the means of delivering the neurostimulation signal. PTNS uses a percutaneous delivery system where a minimally invasive needle is inserted into the skin above the medial malleolus and serves as an electrode,

The ZIDA Wearable Neuromodulation System (ZIDA, LLC) consists of a control unit (a battery-powered neuromodulation pulse generator) that connects to the ZIDA control sock. The electrodes are embedded in the sock so that the top electrode will be approximately 5 cm cephalad to the medial malleolus and the second electrode over the ipsilateral calcaneus. The ZIDA Wearable Neuromodulation System is indicated to treat patient with an overactive bladder (OAB) and associated symptoms of urinary urgency, urinary frequency, and urge incontinence (FDA 510(k) clearance: Product Code: NAM, K192731, March 19, 2021).

The Vivaly System Wearable Non-Invasive Neuromodulation System and Mobile Application (Avation Medical, Inc.) is a wearable neuromodulation system consisting of a controller (stimulator) with rechargeable battery, wearable ankle garment, gel cushions, and accessories. Two electrodes are integrated into the wearable ankle garment. Integrated EMG sensing at the dorsal foot continuously monitors nerve recruitment during therapy. The Vivaly System is indicated to treat patients with the bladder conditions of urge urinary incontinence and urinary urgency (FDA 510(k) clearance: Product Code: NAM, K220454. April 3, 2023).

PTNS/TTNS differ from transcutaneous electrical nerve stimulation (TENS). TENS's mechanism of action aims to provide a degree of symptomatic pain relief by stimulating the pain gate mechanism. PTNS/TTNS's mechanism of action delivers electrical pulses to the sacral nerve plexus via the tibial nerve. In simple terms, the goal of TENS is to distract the brain from physical stimuli, whereas the goal of PTNS/TTNS is to prevent the brain from sending the wrong signals to the bladder plexus.

The ZIDA System was evaluated in a prospective, randomized, single-blind, placebo-controlled study of subjects divided into two groups, with one group having the active ZIDA device treatment once weekly at home, and one group having a sham ZIDA device (non-treatment) once weekly, for a duration of 12 weeks for both groups (ClinicalTrials.gov Identifier NCT04470765). Subjects were called by a research associate weekly to report their weekly treatment and any complications during the 12-week treatment period. A third party will be assigned to label the

devices prior to distribution to the study center. The 3rd party will maintain blinding of the device labelling/ assignment codes until the trial completion. The study enrolled subjects with overactive bladder (OAB). Subject eligibility was based on meeting the criteria for an OAB, defined by the International Continence Society as an average urinary frequency:  $\geq 8$  voids and  $\geq 1$  urgency episode (with or without incontinence) per 24 hours. Subjects were excluded if they were on antimuscarinic medications for OAB and did not go through a 2-week run-in washout period during which time medications were discontinued. Results of the study (Transcutaneous Tibial Nerve Stimulation: the ZIDA Device Equivalence) are published by Cava and Orlin, 2022). Forty patients with diagnosed with OAB were recruited from a single site. The treatment group consisted of 21 patients, mean age 64, which used an active ZIDA device and the sham control group consisted of 19 patients, mean age 72). Patients were randomized in a 1:1 ratio. After individual fitting of the sock and face-to-face instruction in the use of the device, patients in both groups self-administered the treatment once weekly for 30 min at home for a duration of 12 weeks. Prior to randomization and in Week 12, patients completed two 3-day bladder diaries and a quality-of-life (QOL) survey. Treatment success was defined as at least a 50% reduction in urgency voids with or without incontinence or at least a 30% reduction in 24-h frequency from baseline to Week 12. The key secondary endpoint was change in QOL from baseline to Week 12. The success rate for the primary endpoint in the ZIDA group was 80% ( $n = 16/20$ ) versus 39% ( $n = 7/18$ ) in the SCG ( $p = 0.02$ ). For QOL, the least squares mean difference in change from baseline to Week 12 between the ZIDA and sham control arms total score was  $-12.7$  (95% CI  $-20.2$  to  $-5.1$ ). No significant adverse effects were observed.

The Vivally System was evaluated in a multicenter, open-label, single-arm 12-week study (FREEOAB Study for Overactive Bladder, ClinicalTrials.gov Identifier: NCT04547920). FREEOAB evaluated changes from baseline in OAB symptoms as measured by bladder diaries and quality of life (QoL) instruments through 12 weeks of therapy. Inclusion in the study required adult subjects to have been diagnosed or have symptoms of OAB for  $\geq 3$  months, with an average of  $\geq 10$  daily voids on a 3-day bladder diary. Each subject had to have a detectable electromyography (EMG) signal with the system, tolerate a 30-minute therapy session, and agree to remain either drug-naive, or stable on any OAB medication regimen. This study was comprised of two phases. In phase I, subjects were asked to use the device for 1-3 thirty-minute sessions per week for 12 weeks. Upon completion of phase I, subjects were given the opportunity to continue treatment with the system beyond the initial 12 weeks, provided they were compliant with therapy and data collection. Subjects signed a new informed consent and continued to complete bladder diaries prior to each phase II visit. Phase II efficacy results were analyzed after all subjects completing their 6-month and 12-month visits. During phase II patients tapered therapy to only two 30-minute sessions per month. Results of FREEOAB Study for Overactive Bladder are published by Goudelocke et al., 2024. Phase I analysis included the Intent-to-Treat (ITT) population: all subjects enrolled in the study, regardless of whether they completed phase I ( $N = 96$ ). Comparison of 3-day diary parameters between baseline and 12-week diaries demonstrated significant reductions in each domain. Voiding events in 89 (94.7%) subjects reporting UF showed a mean reduction of  $2.84 \pm 2.4$  ( $P < .0001$ ) from baseline. Incontinence episodes in 76 (80.8%) subjects were reduced by  $1.91 \pm 3.1$  ( $P < .0001$ ), and urgency episodes in 74 (78.7%) subjects decreased by  $3.09 \pm 3.9$  ( $P < .0001$ ). In evaluating changes in QOL with the OAB-q questionnaire, a Minimal Clinically Important Difference (MCID) of 10 points was utilized. Changes in the OAB-q health related quality of life (HRQL) domains (coping, concern/worry, sleep, and social interaction) all exceeded the MCID, with most domains at least twice the MCID. Subjects who completed the 12-week phase and met criteria were provided with the opportunity to continue treatment beyond the initial 12-week assessment in Phase II of the study. A total of 50 patients elected to enroll in continued therapy, with 47 (94%) and 39 (78%) subjects completing therapy for 6 and 12-month analyses, respectively. Improvement in diary parameters persisted at 6-month with mean reductions in UF events of  $2.67 \pm 2.5$  ( $P < .0001$ ), of UUI episodes of  $2.13 \pm 3.0$  ( $P < .0001$ ), and of UU episodes of  $3.97 \pm 5.2$  ( $P < .0001$ ). Improvement in diary parameters (Fig. 3) remained robust across all symptoms at 12 months with mean reductions in UF events of  $1.85 \pm 2.8$  ( $P < .0001$ ), of UUI episodes of  $1.29 \pm 3.9$  ( $P = .0556$ ), and of UU episodes of  $2.84 \pm$

4.9 (P = .0040). Durability of therapy persisted in long-term follow-up despite the requirement that frequency of therapy was gradually reduced to twice per month after the first 12 weeks.

The Vivaly System was also evaluated in a multicenter, prospective, randomized, double-blind, sham-controlled study comparing the response of OAB symptoms tracked with a patient electronic voiding diary through 12 weeks of therapy (REDUCEOAB, ClinicalTrials.gov Identifier: NCT05381116). Patients were randomized 1:1 (active arm: sham arm) and instructed to utilize the system 3 times weekly for 30-minute sessions. Both subjects and study site staff responsible for collecting data were blinded to the allocation. Patients were allowed to continue concomitant OAB medications if therapy was stable and they remained on a consistent regimen throughout the study. The primary efficacy endpoint was a responder rate, defined as  $\geq 50\%$  reduction in daily urgency leaks or a  $\geq 30\%$  reduction in daily voids from baseline recorded on an electronic voiding diary. Safety was evaluated through adverse event (AE) reporting and patient satisfaction with the system was recorded. Of the 211 subjects screened, a total of 125 subjects were randomized. In total, 111/125 (88.8%) of randomized patients completed follow-up at 12 weeks, with most patients discontinuing due to technical issues (n = 5) or protocol deviation (n = 5). Only 3/125 (2.4%) chose to withdraw for personal reasons (n = 2) or an unrelated adverse event (n = 1).

The Intent-to-Treat (ITT) Population comprised all subjects enrolled in the study, regardless of whether they completed 12 weeks of therapy (N = 125). A modified Intent-to-Treat (mITT) population (N = 107) was comprised of a subset of the ITT population but excluded subjects who were randomized incorrectly or followed an incorrect study arm protocol, either due to user error or device deficiency or those who had no evaluable diary data at baseline. The mITT population resulted in 55 patients in the active device arm and 52 in the sham arm. The enrolled population was used for safety outcome analysis. The mITT population was used as the primary population for all efficacy analyses. The mITT population showed a statistically significant higher responder rate of 83.6% for the active arm compared with 57.7% for the sham arm (P = .032). Additional secondary analysis was done for individual symptoms, demonstrating a responder rate for Voids of 57.1% for the active arm compared to 40.5% for a sham arm. Similarly, responder rate for leaks was 71.8% for active arm and 59.5% for sham arm. In contrast, analysis of improvement by specific symptom did not distinguish the active arm from the sham arm, with mean improvement from baseline in voids of  $3.7 \pm 4.4$  for active and  $3.4 \pm 6.0$  for sham, and for urgency leaks of  $2.6 \pm 2.6$  for active and  $3.1 \pm 4.1$  for sham. There were no serious adverse events; of non-serious, device-related events, 13/20 (65.0%) were considered mild. The most common related event was pain or ache/ cramping of the foot or ankle (n = 8). Only 1/125 patients (0.8%) discontinued the study due to an adverse event determined to be unrelated to the system. As all patients utilized the complete system, including garment and mobile application, patient usability data from both arms is relevant. In total, 92 patients completed usability and satisfaction questionnaires, with 90/92 (97.8%) reporting they were moderately to extremely satisfied with the companion application and 92/92 (100%) reporting similar satisfaction with the garment. All patients reported it was moderately to extremely easy to fit the therapy into their routine, and 88/92 (95.6%) felt similarly about the likelihood of using the system to treat their OAB in the future.

## **Analysis of Evidence (Rational for Determination)**

Regarding transcutaneous tibial nerve stimulation (TTNS), by enabling home-based therapy with objective confirmation of tibial nerve activation, this system may address several barriers to OAB treatment compliance, including time commitment, cost, and patient accessibility. Integrating a digital health platform that facilitates symptom and behavioral tracking and remote monitoring of therapy progress by providers enhances usability and engagement. Future studies should focus on long-term outcomes and real-world effectiveness to validate these promising results.

## **Coding**

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Code	Description
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming

### ICD-10-CM codes that support medical necessity for PTNS

In the outpatient setting, the term first-listed diagnosis is used in lieu of principal diagnosis. The first-listed diagnosis code must best describe the patient's condition for which the service was performed.

ICD-10-CM	Description
N32.81*	Overactive bladder
N39.41	Urge incontinence
R35.0	Frequency of micturition
R39.15	Urgency of urination

\* ICD-10-CM code N32.81 should be reported for overactive bladder syndrome.

### Percutaneous Implantation of Integrated Neurostimulation System

On October 19, 2016, CMS approved Medicare coverage for the Category B IDE study associated with the Protect PNS device (G150178); the PROTECT study sponsored by Uro Medical Corporation, ClinicalTrials.gov ID NCT02577302. Category B IDE studies are covered by Fallon Health for Medicare Advantage plan members only, including Fallon Medicare Plus and NaviCare HMO SNP (dual eligible Medicare/Medicaid).

The following codes are covered for Medicare Advantage plan members, including Fallon Medicare Plus and NaviCare HMO SNP (dual eligible Medicare/Medicaid), only when the member is enrolled in Category B IDE study G150178 – the “PROTECT” Study.

Code	Description
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
0589T	Electronic analysis with simple programming of implanted integrated neurostimulation system (e.g. 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 (e.g. 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 healthcare professional, posterior tibial nerve, 4 or more parameters

## References

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## Policy history

Origination date:	11/27/2007
Review/Approval(s):	Technology Assessment Committee: 04/08/2008, 12/16/2009, 01/25/2011, 06/28/2011, 08/28/2013, 02/25/2015 (updated references, now covered for all lines of business) 03/23/2016 (removed ICD-9 codes, updated references), 04/26/2017 (clarified service is experimental for Commercial Plans, updated references), 05/15/2018 (updated references), 05/22/2019 (updated references), 07/10/2021 (added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section), 07/27/2021, 08/27/2024 (annual review, updated Medicare regulatory information in Policy section, clarified coverage criteria, updated References and Coding section), 09/23/2025 (annual review, added Summary of Evidence and Analysis of Evidence for transcutaneous tibial nerve stimulation, no changes to coverage criteria). Utilization Management Committee: 10/21/2025 (approved with no changes to coverage criteria).

## Instructions for Use

Fallon Health complies with CMS’s national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan’s service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Fallon Health generally follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

For plan members enrolled in NaviCare, Fallon Health first follows CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.