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).

Medicare Advantage
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).

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 08/23/2024).

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 ACO
Fallon Health 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.

MassHealth does not have Guidelines for Medical Necessity Determination for posterior tibial nerve stimulation (MassHealth website search 08/23/2024), therefore, the Plan's coverage criteria are applicable.

NaviCare HMO SNP, NaviCare SCO
For plan members enrolled in NaviCare, Fallon Health first follow's 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.

PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
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.

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.

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), HCPCS code E0736 (Transcutaneous tibial nerve stimulator) is considered experimental/investigational and not medically necessary. 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.

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

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

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), 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

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Policy history

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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.