



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.

Definitions

Urge Urinary Incontinence: The complaint of involuntary leakage (of urine) accompanied by or immediately preceded by urgency.

Stress Urinary Incontinence: The complaint of involuntary leakage (of urine) on effort or exertion, or on sneezing or coughing.

Nocturia: The complaint that the individual has to wake at night one or more times to urinate.

Increased Daytime Frequency: The complaint by the individual who considers that he/she voids too often during the day.

Urgency: The complaint of a sudden compelling desire to pass urine, which is difficult to defer.

Urinary incontinence: The complaint of any involuntary leakage of urine.

Policy

This Policy applies to the following Fallon Health products:

- Commercial
- Medicare Advantage
- MassHealth ACO
- NaviCare
- PACE

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare does not have an NCD for posterior tibial nerve stimulation. National Government Services, Inc. has an LCD for Posterior Tibial Nerve Stimulation for Voiding Dysfunction (L33396) and an LCA Billing and Coding: Posterior Tibial Nerve Stimulation for Voiding Dysfunction (A57453) (MCD search 06-29-2021).

For plan members enrolled in NaviCare and PACE plans, Fallon Health follows Medicare guidance for coverage determinations. In the event that there is no Medicare guidance or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health will follow guidance published by MassHealth. When there is no Medicare or MassHealth guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members. Each PACE plan member is assigned to an Interdisciplinary Team. When there is no Medicare or MassHealth guidance, the member's Interdisciplinary Team is responsible for coverage determinations.

Posterior tibial nerve stimulation (PTNS) requires prior authorization. Requests must be supported by medical records from the treating provider(s).

Commercial plan members: PTNS is considered experimental and investigational, thus non-covered.

MassHealth plan members: PTNS is covered when the following criteria are met:

1. Fallon Health will authorize one (per lifetime) 12-week treatment regimen (consisting of 30 minute sessions given once weekly for 12 consecutive weeks) for the treatment of symptoms of OAB that is either refractory or intolerant to standard anticholinergic drug therapy (i.e., failed treatment with at least two anticholinergic drugs each taken for at least 4 weeks duration prior to the initiation of PTNS).
2. Fallon Health will authorize continuation of PTNS for plan members who complete and show response to the 12-week treatment regimen. Response is defined as at least a 50% improvement in voiding symptoms (based on documentation such as patient voiding diaries). The treatment regimen for continued PTNS is tailored to each individual plan member; typically one treatment is administered every 2 to 3 weeks (26 treatments per 12 month maximum).

Medicare Advantage, NaviCare and PACE plan members: Fallon Health follows coverage criteria in National Government Services, Inc. LCD for Posterior Tibial Nerve Stimulation for Voiding Dysfunction (L33396) and LCA Billing and Coding: Posterior Tibial Nerve Stimulation for Voiding Dysfunction (A57453).

LCD link: [Posterior Tibial Nerve Stimulation for Voiding Dysfunction \(L33396\)](#)

Exclusions

- Any use of posterior tibial nerve stimulation other than outlined above.

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

The use of one of the ICD-10-CM codes listed below does not assure coverage of PTNS. PTNS is covered for Medicare and MassHealth plan members and requires prior authorization.

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

References

1. National Government Services, Inc. Local Coverage Determination (LCD): Posterior Tibial Nerve Stimulation for Voiding Dysfunction (L33396). Original Effective Date October 1, 2015. Revision Effective Date 10/24/2019. Available at: <https://www.cms.gov/medicare-coverage-database/new-search/search.aspx>. Accessed June 29, 2021.
2. National Government Services, Inc. Local Coverage Article: Billing and Coding: Posterior Tibial Nerve Stimulation for Voiding Dysfunction (A57453). Original Effective Date 10/24/2019. Available at: <https://www.cms.gov/medicare-coverage-database/new-search/search.aspx>. Accessed June 29, 2021.
3. Goode PS. Behavioral and Drug Therapy for Urinary Incontinence. *Urology* 2004 Mar;63(Suppl 3A):58-64.
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6. MacDiarmid SA, Peters KM, Shobeiri A, et al. Long-Term Durability of Percutaneous Tibial Nerve Stimulation for the Treatment of Overactive Bladder. *J Urol*. 2010;183:234-40.
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12. Gormley EA, Lightner DJ, Burgio KL, et al. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU guideline. *J Urol*. 2012 Dec;188(6 Suppl):2455-63.
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Policy history

Origination date:	11/27/2007
Approval(s):	ICD10 codes: Mapped 02/26/2014, 04/23/2014 (correction due to ICD-10-CM implementation) 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), <i>07/10/2021 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section.</i>

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.