



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

Fallon Health requires prior authorization for Posterior Tibial Nerve Stimulation (PTNS). These requests must be supported by the treating provider(s) medical records.

For Commercial Plan Members this service is considered experimental and investigational, thus non-covered.

For all other lines of business the below criteria must be met.

PTNS requires prior authorization from Fallon Health.

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).

Exclusions

- Any use of Posterior Tibial Nerve Stimulation other than outlined above.

Codes

Code type	Code	Description
CPT	64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming
ICD-10-CM	N39.41	Urge incontinence
	N39.42	Incontinence without sensory awareness
	N39.45	Continuous leakage
	N39.46	Mixed incontinence
	R35.0	Frequency of micturition

	R39.15	Urgency of Urination
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References

1. National Government Services Inc. Local Coverage Determination (LCD) L33396 Posterior Tibial Nerve Stimulation for Voiding Dysfunction. Effective October 1, 2015
2. Hayes Inc. Hayes Directory: Percutaneous Tibial Nerve Stimulation for the Treatment of Symptomatic Neurogenic Lower Urinary Tract Dysfunction. Published April 15, 2019
3. Goode PS. Behavioral and Drug Therapy for Urinary Incontinence. Urology 2004 Mar;63(Suppl 3A):58-64.
4. Govier FE, Litwiller S, Nitti V, Kreder KJ Jr, Rosenblatt P. Percutaneous Afferent Neuromodulation for the Refractory Overactive Bladder: Results of a Multicenter Study. J Urol 2001 Apr;165:1193-98.
5. van Balken MR, Vergunst H, Bemelmans BL. Prognostic Factors for Successful Percutaneous Tibial Nerve Stimulation. Eur Urol. 2006 Feb;49(2):360-5.
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7. Peters KM, Carrico DJ, Wooldridge LS, Miller CJ, MacDiarmid SA. Percutaneous tibial nerve stimulation for the long-term treatment of overactive bladder: 3-year results of the STEP study. J Urol. 2013 Jun; 189(6):2194-201.
8. Rai BP, Cody JD, Alhasso A, Stewart L. Anticholinergic drugs versus non-drug active therapies for non-neurogenic overactive bladder syndrome in adults. Cochrane Database Syst Rev. 2012;12:CD003193.
9. Gaziev G, Topazio L, Iacovelli V, et al. Percutaneous tibial nerve stimulation (PTNS) efficacy in the treatment of lower urinary tract dysfunctions: a systematic review. BMC Urol. 2013;13:61.
10. Moosdorff-Steinhauser HF, Berghmans B. Effects of percutaneous tibial nerve stimulation on adult patients with overactive bladder syndrome: a systematic review. Neurourol Urodyn. 2013;32(3):206-214.
11. de Wall LL, Heesakkers JP. Effectiveness of percutaneous tibial nerve stimulation in the treatment of overactive bladder syndrome. Res Rep Urol. 2017 Aug 14;9:145-157. doi: 10.2147/RRU.S124981. eCollection 2017.

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)

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. For Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this policy.