Policy Title:	Policy - Percutaneous Tibial Nerve Stimulation (PTNS) Therapy for Voiding Dysfunction	Number & Version:	UM-PTNS v4
Functional Unit:	Utilization Management	Effective Date:	04/18/2025
Policy Owner (Title):	Senior Director, Utilization Management	Page Number:	1 of 4

I. POLICY STATEMENT and PURPOSE

In its administration of Medicare Advantage plans (Health Plans), the Company shall determine benefits in accordance with the requirements of the Centers for Medicare & Medicaid Services (CMS). Where CMS has established a national coverage policy on an item or service or a local Medicare contractor has done so as authorized by CMS, the Company follows the Medicare coverage policy. In the absence of fully established Medicare coverage criteria, the Company may develop and implement internal criteria based on current evidence in widely used treatment guidelines or clinical literature. Internal criteria are reviewed and approved by the Medical Management Committee and are made publicly accessible.

CMS has not established national coverage criteria for Percutaneous Tibial Nerve Stimulation (PTNS) therapy for Voiding Dysfunction, therefore the Company has developed and implemented this coverage policy to ensure that patients receive clinically appropriate, medically necessary care at the appropriate level, which allows for the best clinical outcome and prevents harm such as inpatient acquired illness. The purpose of this policy is to describe the circumstances under which PTNS therapy would be considered medically necessary.

II. BACKGROUND

The International Continence Society (ICS) now recognizes overactive bladder syndrome (OBS) as a "symptom syndrome suggestive of lower urinary tract dysfunction." It is specifically defined as "urgency, with or without urge incontinence, usually with frequency and nocturia" (Wein, 2002).

There are multiple treatments available for the management of OBS. Treatment guidelines recommend behavioral and pharmacotherapy (medication therapy) as first-line treatment options for OBS. Referrals to appropriate specialists are usually indicated when patients to do not respond to first-line treatment. PTNS has been shown to be effective for patients who have not responded adequately to first-line treatment (Hayes, 2022).

III. SCOPE

This Policy applies to Percutaneous Tibial Nerve Stimulation (PTNS) therapy for Voiding Dysfunction.

IV. DEFINITIONS

PTNS - Percutaneous Tibial Nerve Stimulation (PTNS) is a lower urinary tract neuromodulation technique performed by percutaneous electrical stimulation of the posterior tibial nerve. A needle is inserted near the tibial nerve followed by low voltage electrical stimulation but can also be delivered using surface electrodes instead.

Medically Necessary – Covered Services rendered by a Health Care Provider that the Plan determines are:

1) Safe and effective
2) Not experimental or investigational
3) Appropriate for patients,
   a) including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is—
      i) furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member,
      ii) furnished in a setting appropriate to the patient's medical needs and condition,
      iii) ordered and furnished by qualified personnel,
      iv) one that meets, but does not exceed, the patient's medical need; and
      v) are at least as beneficial as existing and available medically appropriate alternatives.

V. OWNERSHIP & TRAINING

The Senior Director, Utilization Management is responsible for administration, oversight, and training regarding performance under this Policy.

VI. PROTOCOLS / COVERAGE POLICY

The Protocols/Coverage policies that follow pertain ONLY to the following states: AR, KY, IN, MO, OH, MI

Studies have reported that PTNS is safe with statistically significant improvements in the clinical assessment of OBS and may be considered a clinically significant alternative to failed pharmacotherapy.

a. Initial PTNS treatment is considered medically necessary for patients with a diagnosis of OBS as a less invasive "third-line treatment" when all the following criteria are met:
   i. An evaluation by an appropriate specialist, usually a urologist, gynecologist, or urogynecologist, has been performed and the specialist has determined that the patient is a candidate for PTNS and has the cognition to void using the appropriate facilities (i.e., restroom).
   ii. Medical record documentation includes compliance with and failed a trial of symptom-appropriate behavioral therapy of sufficient length to evaluate potential efficacy and compliance with, and
   iii. Individual has failed or been unable to tolerate a trial of at least two anticholinergic medications administered for at least four (4) weeks prior to initiating PTNS therapy.

Medical record documentation of intolerance includes medical management used to address the intolerance (such as dry mouth and constipation).

iv. A voiding diary revealing continued findings of OBS.

v. Documentation of the patient's willingness to attend in-office treatment sessions, to comply with the behavioral therapies, and to continue to keep voiding diaries including documentation of compliance with behavioral therapy.

Standard treatment regimen should consist of one 30-minute session per week for 12 weeks.

b. Maintenance and Relapse PTNS therapy coverage indications are as follows:

i. Maintenance Therapy: is allowed if the initial 12 PTNS treatments resulted in improved OBS symptoms. Maintenance treatment may be allowed at a frequency of 1 treatment every 1-2 months when medical necessity is supported by documentation in the medical record. This may continue for up to 3 years (Burkhard, 2020), with a lifetime number of sessions not to exceed 45 in total.

ii. Relapse Therapy: is allowed only for those individuals who achieved greater than 50% decrease in OBS symptoms with initial treatment and then relapse. Relapse treatment is not expected to occur more frequently than 1-2 sessions every 1-2 months.

PTNS treatment is contraindicated for patients with pacemakers or implantable defibrillators, patients prone to excessive bleeding, with nerve damage impacting tibial nerve or pelvic floor function, pregnant women or women planning to become pregnant during PTNS treatment. PTNS devices should be used with caution in patients with heart disease (Hayes, 2022).

VII. SUMMARY OF EVIDENCE

PTNS appears to be an effective non-invasive treatment option for adults with persistent OBS despite standard medical treatment and may fill the treatment gap between pharmacotherapy and irreversible surgical procedures.

VIII. REGULATORY REFERENCES / CITATIONS

CMS National Coverage Determinations (NCDs)	None
CMS Local Coverage Determinations (LCDs)	L33396
CMS Articles	A57453

ID	Title	Type	Service Area	Contractor
L33396	Posterior Tibial Nerve Stimulation for Voiding Dysfunction	LCD	CT, IL, MA, ME, MN, NH, NY, RI, WI, VT	National Government Services, Inc. (MAC - Part A, MAC - Part B)

IX. PROFESSIONAL REFERENCES / CITATIONS

1. Burkhard, F.C; et. al. European Association of Urology (EAU) Guidelines on Urinary Incontinence in Adults. Issued 2020. Accessed March 2025. https://d56bochluxqnz.cloudfront.net/media/EAU-Guidelines-on-Urinary-Incontinence-2020.pdf

2. Hayes. Health Technology Assessment. Comparative Effectiveness Review of Percutaneous Tibial Nerve Stimulation for the Treatment of Symptomatic Non-Neurogenic Overactive Bladder. Issued Oct. 2018. Accessed March 2025. https://evidence.hayesinc.com/report/dir.percutaneous1251

3. Wein, Alan & Rovner, Eric. Definition and Epidemiology of Overactive Bladder. National Library of Medicine-National Center for Biotechnology Information. Issued 2002. Accessed March 2025. https://pubmed.ncbi.nlm.nih.gov/12493342/

APPROVALS:

Chief Medical Officer
(MMC Chair): Saria Saccocio, MD

VERSION HISTORY:

Version	Date	Author	Purpose/Summary of Major Changes
01	08/05/2021	Julie Braundmeier	Original Issue
02	03/03/2022	Gina Vehige	Annual review; no substantive changes. QMMC Decision: approved.
03	05/03/2023	Gina Vehige	Annual review. Updated maintenance therapy frequency & intervals, references and relevant LCDs. Approved by MMC 6/30/2023.
04	05/01/2024	Gina Vehige	Annual review. Updated responsibility designee, references and relevant LCDs. Approved by MMC 6/7/2024.
05	03/31/2025	Sheila Gray / Kerrie Stehl	Annual review. Updated references; updated formatting; no substantive changes to coverage criteria. Approved by MMC 04/16/2025.