Policy Title:	Policy - Percutaneous Tibial Nerve Stimulation (PTNS) Therapy for Voiding Dysfunction	Number & Version:	UM-PTNS v4
Functional Unit:	Utilization Management	Effective Date:	6/7/2024
Policy Owner (Title):	Senior Director, Utilization Management	Page Number:	1 of 6

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 (OAB) 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). The incidence of OAB increases with age and has a known adverse effect on quality of life (Milsom, 2001). Women are more commonly affected, and there is increased incidence with age. African American and Hispanic race is predictive of OAB for men (Coyne 2012).

There are multiple treatments available for the management of OAB. Treatment guidelines recommend treatment that includes behavioral as well as pharmacotherapy. Referrals to specialists are usually indicated when patients to do not respond to first line treatment. PTNS has been shown to be effective for select patients (Bhide, 2020) (Fontaine, 2021) (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 4–5 cm cephalad to the medial malleolus. This has been demonstrated to be a neural access point for the regulation of bladder and pelvic floor function. Electric current is applied at the highest level tolerated by the patient. Stimulation sessions are performed periodically over several weeks (Gaziev, 2013).

(Non) Neurogenic Voiding Dysfunction (Bladder) - Neurogenic voiding dysfunction can also be referred to as neurogenic bladder and is a nervous system disorder in which problems with the brain, nerve(s), or spinal cord affect bladder control. Non-neurogenic voiding dysfunction has no cause related to the brain, nerves, or spinal cord and is usually related to a weak bladder muscle, a blockage in the flow of urine, or habits that have developed over time (Cleveland Clinic, 2021).

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) is 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

The following state is governed by LCD 33396: IL; as described in section VIII.

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

a. Coverage indications / medical necessity is met for those with a diagnosis of overactive bladder syndrome (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 (ie., 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 therapy coverage indications are as follows:

   i. After the initial 12 sessions, patients with the improved OAB symptoms of frequency, nocturia, urgency, voided volume and urge incontinence episodes, may be allowed maintenance treatment 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 a maximum of 3 years (Burkhard, 2020), with a lifetime number of sessions not to exceed 45 in total.

   ii. Posterior tibial nerve stimulation treatment for relapse is allowed only for those individuals who achieve greater than 50% decrease in OBS symptoms, and relapse

following the initial treatment. Relapse treatments are not expected to occur more frequently than one to two sessions every one to two months.

PTNS treatment is contraindicated for patients with pacemakers or implantable defibrillators, patients prone to excessive bleeding, patients with nerve damage that could impact either percutaneous tibial nerve or pelvic floor function, or patients who are pregnant or planning to become pregnant during the duration of the treatment. Caution should be exercised for patients with heart problems related to pacing.

(Bhide, 2020) (Finazzi-Agrò, 2010) (Fontaine, 2021) (Hayes, 2022) (Wang, 2020)

VII. SUMMARY OF EVIDENCE

PTNS appears to be an effective treatment option for adults with OAB symptoms that persist despite standard medical therapy. PTNS therapy may fill the treatment gap between pharmacotherapy and irreversible surgical procedures.

(Bhide, 2020) (Finazzi-Agrò, 2010) (Fontaine, 2021) (Hayes, 2022) (Wang, 2020)

VIII. REGULATORY REFERENCES / CITATIONS

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

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)

(CMS, Posterior Tibial Nerve Stimulation (PTNS), 2024)

IX. PROFESSIONAL REFERENCES / CITATIONS

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X. RELATED POLICIES / PROCEDURES

None

XI. ATTACHMENTS

See section VIII.

APPROVALS:

	Printed Name	Signature
Senior Medical Officer: (MMC Chair)	Michael Fusco, MD	
Corporate Chief Medical Officer:	Debbie Zimmerman, MD	

VERSION HISTORY:

Version #	Date	Author	Purpose/Summary of Major Changes
01	08/05/2021	Julie Braundmeier	Original Issue
02	3/3/2022	Gina Vehige	Review: QMMC Decision: approved
03	05/03/2023	Gina Vehige	Updated maintenance therapy frequency & intervals. Updated reference. Updated relevant LCDs. FINAL Approved by MMC 6/30/2023; Effective 07/10/2023
04	05/01/2024	Gina Vehige	Updated responsibility designee, updated references, updated LCDs, reformatted, updated approver titles, no essential change to final recommendations. Approved by MMC 6/7/2024.