

**POLICY & PROCEDURE**

Policy Title:	Policy - Percutaneous Tibial Nerve Stimulation (PTNS) Therapy for Voiding Dysfunction	Number & Version:	UM-PTNS23
Functional Unit:	Utilization Management	Effective Date:	07/10/2023
Policy Owner (Title):	Director, Utilization Management	Page Number:	1 of 7

**I. POLICY STATEMENT and PURPOSE**

The purpose of this policy is to describe the circumstances under which Percutaneous Tibial Nerve Stimulation (PTNS) therapy for voiding dysfunction would or would not be considered medically necessary for members under the guidelines used for clinical review of organizational determinations.

**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 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.

**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).



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Functional Unit:	Utilization Management	Effective Date:	07/10/2023
Policy Owner (Title):	Director, Utilization Management	Page Number:	2 of 7

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

### VI. PROTOCOLS / COVERAGE POLICY

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 weeks prior to initiating PTNS therapy.



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Functional Unit:	Utilization Management	Effective Date:	07/10/2023
Policy Owner (Title):	Director, Utilization Management	Page Number:	3 of 7

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.



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Policy Owner (Title):	Director, Utilization Management	Page Number:	4 of 7

**VII. REGULATORY REFERENCES / CITATIONS**

CMS National Coverage Determinations (NCDs) None  
 CMS Local Coverage Determinations (LCDs) see table next

L33443	Posterior Tibial nerve Stimulation (PTNS) for Urinary Control	LCD	Palmetto GBA (MAC - Part B)
L33396	Posterior Tibial Nerve Stimulation for Voiding Dysfunctions	LCD	National Government Services, Inc. (MAC - Part A, MAC - Part B)

(CMS, Posterior Tibial Nerve Stimulation (PTNS) for Urinary Control, 2023)

**VIII. PROFESSIONAL REFERENCES / CITATIONS**

- Bhide, Alka A et al. "Posterior tibial nerve stimulation for overactive bladder-techniques and efficacy." *International urogynecology journal* vol. 31,5 (2020): 865-870. doi:10.1007/s00192-019-04186-3 Accessed at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7210232/> on May 3, 2023.
- Fontaine, C., Papworth, E., Pascoe, J., & Hashim, H. (2021). Update on the management of overactive bladder. *Therapeutic advances in urology*, 13, 17562872211039034. <https://doi.org/10.1177/17562872211039034>. Accessed at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8411623/> on May 3, 2023.
- Centers for Medicare and Medicaid Services (CMS). Medicare Coverage Database. Search Results. Posterior Tibial Nerve Stimulation (PTNS). Accessed at: <https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=Posterior%20Tibial%20Nerve%20Stimulation&keywordType=starts&areaId=all&docType=NCD,F,P&contractOption=all&sortBy=relevance> Accessed on: May 3, 2023.
- Cleveland Clinic. Health Library. Diseases & Conditions. Non-Neurogenic Voiding Dysfunction. March 1, 2021. Accessed at: <https://my.clevelandclinic.org/health/diseases/16394-non-neurogenic-voiding-dysfunction> on May 3, 2023.
- Coyne, K. S., Margolis, M. K., Kopp, Z. S., & Kaplan, S. A. (2012). Racial differences in the prevalence of overactive bladder in the United States from the epidemiology of LUTS (EpiLUTS) study. *Urology*, 79(1), 95–101. <https://doi.org/10.1016/j.urology.2011.09.010>. Accessed at: <https://pubmed.ncbi.nlm.nih.gov/22055692/> on May 3, 2023.



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Functional Unit:	Utilization Management	Effective Date:	07/10/2023
Policy Owner (Title):	Director, Utilization Management	Page Number:	5 of 7

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7. Gaziev, G., Topazio, L., Iacovelli, V., Asimakopoulos, A., Di Santo, A., De Nunzio, C., & Finazzi-Agrò, E. (2013). Percutaneous Tibial Nerve Stimulation (PTNS) efficacy in the treatment of lower urinary tract dysfunctions: a systematic review. *BMC urology*, 13, 61. <https://doi.org/10.1186/1471-2490-13-61> . Accessed at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4222591/> on May 3, 2023.
8. Hayes. Health Technology Annual Review. Comparative Effectiveness Review of Percutaneous Tibial Nerve Stimulation for the Treatment of Symptomatic Non-Neurogenic Overactive Bladder Syndrome. November 15, 2022. Accessed at: <https://evidence.hayesinc.com/report/ar.percutaneous1251> on May 3, 2023.
9. Milsom, I., Abrams, P., Cardozo, L., Roberts, R. G., Thüroff, J., & Wein, A. J. (2001). How widespread are the symptoms of an overactive bladder and how are they managed? A population-based prevalence study. *BJU international*, 87(9), 760–766. <https://doi.org/10.1046/j.1464-410x.2001.02228.x>. Accessed at: <https://pubmed.ncbi.nlm.nih.gov/11412210/> on May 3, 2023.
10. Wein, A. J., & Rovner, E. S. (2002). Definition and epidemiology of overactive bladder. *Urology*, 60(5 Suppl 1), 7–12. [https://doi.org/10.1016/s0090-4295\(02\)01784-3](https://doi.org/10.1016/s0090-4295(02)01784-3). Accessed at: <https://pubmed.ncbi.nlm.nih.gov/12493342/> on May 3, 2023.

### **IX. RELATED POLICIES / PROCEDURES**

None

### **X. ATTACHMENTS**

See section VII.



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Functional Unit:	Utilization Management	Effective Date:	07/10/2023
Policy Owner (Title):	Director, Utilization Management	Page Number:	6 of 7

**APPROVALS:**

Printed Name

Signature

Senior Medical Director,  
UM:

Michael Fusco, MD

Corporate Chief Medical  
Officer (QMMC Chair):

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



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Policy Owner (Title):	Director, Utilization Management	Page Number:	7 of 7

### Medicare Administrative Contractors (MACs) As of June 2021

MAC Jurisdiction	Processes Part A & Part B Claims for the following states/territories:	MAC
DME A	Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont	Noridian Healthcare Solutions, LLC
DME B	Illinois, Indiana, Kentucky, Michigan, Minnesota, Ohio, Wisconsin	CGS Administrators, LLC
DME C	Alabama, Arkansas, Colorado, Florida, Georgia, Louisiana, Mississippi, New Mexico, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, West Virginia, Puerto Rico, U.S. Virgin Islands	CGS Administrators, LLC
DME D	Alaska, Arizona, California, Hawaii, Idaho, Iowa, Kansas, Missouri, Montana, Nebraska, Nevada, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming, American Samoa, Guam, Northern Mariana Islands	Noridian Healthcare Solutions, LLC
5	Iowa, Kansas, Missouri, Nebraska	Wisconsin Physicians Service Government Health Administrators
6	Illinois, Minnesota, Wisconsin <b>**HH + H for the following states:</b> Alaska, American Samoa, Arizona, California, Guam, Hawaii, Idaho, Michigan, Minnesota, Nevada, New Jersey, New York, Northern Mariana Islands, Oregon, Puerto Rico, US Virgin Islands, Wisconsin and Washington	National Government Services, Inc.
8	Indiana, Michigan	Wisconsin Physicians Service Government Health Administrators
15	Kentucky, Ohio <b>**HH + H for the following states:</b> Delaware, District of Columbia, Colorado, Iowa, Kansas, Maryland, Missouri, Montana, Nebraska, North Dakota, Pennsylvania, South Dakota, Utah, Virginia, West Virginia, and Wyoming	CGS Administrators, LLC
E	California, Hawaii, Nevada, American Samoa, Guam, Northern Mariana Islands	Noridian Healthcare Solutions, LLC
F	Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming	Noridian Healthcare Solutions, LLC
H	Arkansas, Colorado, New Mexico, Oklahoma, Texas, Louisiana, Mississippi	Novitas Solutions, Inc.
J	Alabama, Georgia, Tennessee	Palmetto GBA, LLC
K	Connecticut, New York, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont <b>**HH + H for the following states:</b> Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont	National Government Services, Inc.
L	Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania (includes Part B for counties of Arlington and Fairfax in Virginia and the city of Alexandria in Virginia)	Novitas Solutions, Inc.
M	North Carolina, South Carolina, Virginia, West Virginia (excludes Part B for the counties of Arlington and Fairfax in Virginia and the city of Alexandria in Virginia) <b>**HH + H for the following states:</b> Alabama, Arkansas, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Mississippi, New Mexico, North Carolina, Ohio, Oklahoma, South Carolina, Tennessee, and Texas	Palmetto GBA, LLC
N	Florida, Puerto Rico, U.S. Virgin Islands	First Coast Service Options, Inc.

**\*\*Also Processes Home Health and Hospice claims**