Clinical Policy: Posterior Tibial Nerve Stimulation for Voiding Dysfunction

Reference Number: LA.CP.MP.133 Coding Implications
Last Review Date: 08/2020 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Posterior tibial nerve stimulation (PTNS), also known as peripheral tibial nerve stimulation, is a minimally invasive form of electrical neuromodulation used to treat overactive bladder (OAB) syndrome and associated symptoms of urinary urgency, urinary frequency, and urge urinary incontinence. This policy describes the medical necessity requirements for posterior tibial nerve stimulation.

Policy/Criteria

I. It is the policy of Louisiana Healthcare Connections that PTNS is medically necessary for the treatment of moderate to severe urinary dysfunction and OAB symptoms when all of the following criteria are met:
- **A.** Urinary dysfunction has persisted for at least 12 months and the condition has resulted in significant disability (i.e., the urinary urgency, frequency, and/or severity of symptoms are limiting the member's ability to participate in activities of daily living); and
- **B.** There has been a failure of, contraindications to, or intolerance to conservative medical management (e.g. pharmacotherapy with oral anti-muscarinics or β3-adrenoceptor agonists and/or antibiotics for urinary tract infections); and
- **C.** Service is provided in accordance with the standard treatment regimen of 30-minute weekly sessions for 12 weeks.

II. It is the policy of Louisiana Healthcare Connections that once a month maintenance treatments with PTNS are medically necessary for patients who experience significant improvement in their OAB symptoms after the 12 initial treatments. Treatment frequency may vary depending on return of symptoms.

III. It is the policy of Louisiana Healthcare Connections that PTNS beyond 12 months or when there is no improvement in urinary dysfunction is investigational.

IV. It is the policy of Louisiana Healthcare Connections that implantable tibial nerve stimulation for the treatment of urinary voiding dysfunction is investigational.

Background

The term “voiding dysfunction" has been used to refer to urinary incontinence, urinary retention, and symptoms of frequency and urgency. OAB is a specific type of voiding dysfunction that includes any of the following symptoms: urinary frequency, urinary urgency, urge incontinence, and nocturia. OAB can significantly impact quality of life including physical function, sexual function, and social interactions. Treatments for OAB include lifestyle changes, bladder training, pelvic floor muscle training and anticholinergic (anti-muscarinic) drugs.

PTNS involves indirect modulation of the specific nerve that controls bladder function (i.e., the sacral nerve plexus) via stimulation of the posterior tibial nerve accessed just above the ankle.

This minimally invasive form of neuromodulation consists of insertion of a 34-gauge needle electrode approximately 5 centimeters (cm) cephalad to the medial malleolus and 2 cm posterior to the tibia near the tibial nerve. A surface electrode is placed on the medial aspect of the foot. The needle electrode is connected via a lead wire to a low-voltage electrical stimulator. Stimulation is administered at a current level of 0.5 to 9 milliamperes (mA) at 20 hertz (Hz) and continues for 30 minutes. Initial treatment regimens typically consist of 12 weekly sessions, with responders exhibiting some symptom improvement after 6 to 8 sessions. Maintenance treatment sessions may be required to sustain the response to treatment.[1]

Several implantable tibial nerve neuromodulation systems, including a battery-less leadless, miniature implantable device, are currently under investigation for the management of OAB, however, they have not received FDA approval in the U.S at this time.

National Institute for Health and Care Excellence
Current evidence on PTNS for OAB syndrome shows that it is efficacious in reducing symptoms in the short and medium term. There are no major safety concerns, therefore the procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit.[2]

A NICE guidance on urinary incontinence in women does not recommend the "routine" use of PTNS to treat OAB. Rather, they recommend PTNS for OAB for following:

- There has been a multidisciplinary team (MDT) review, and
- Conservative management including OAB drug treatment has not worked adequately, and
- The woman does not want botulinum toxin A or percutaneous sacral nerve stimulation. [13]

American Urological Association
Clinicians may offer PTNS as third-line treatment in a carefully selected patient population, characterized by moderately severe baseline incontinence and frequency and willingness to comply with the PTNS protocol. Patients must also have the resources to make frequent office visits both during the initial treatment phase and to obtain maintenance treatments in order to achieve and maintain treatment effects. The most common protocol is the application of 30 min of stimulation once a week for 12 weeks (the trial duration; for continued benefit, weekly stimulation would have to continue).[3]

Studies to date evaluating PTNS for the treatment of OAB conclude there is evidence of benefit, although most studies have been small and report short-term outcomes after 12 weeks of treatment. A small study of 33 PTNS responders who continued therapy for 6-12 months reported excellent durability through 12 months.[4] Another small study reported sustained safety and efficacy of PTNS for the treatment of OAB symptom control over 24 months with initial success after 12 weekly treatments, followed by a 14-week prescribed tapering protocol and a personalized treatment plan with an average of 1.3 treatments per month.[5]

Coding Implications
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted

2020, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT codes that support medical necessity

CPT® Codes	Description
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming

CPT codes that do not support medical necessity

CPT® Codes	Description
0587T	Percutaneous implantation or replacement of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming and imaging guidance when performed, posterior tibial nerve
0588T	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve
0589T	Electronic analysis with simple programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, posterior tibial nerve, 1-3 parameters
0590T	Electronic analysis with complex programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, posterior tibial nerve, 4 or more parameters

HCPCS Codes	Description
N/A	

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
N32.81	Overactive bladder
N39.41	Urge incontinence

ICD-10-CM Code	Description
N39.45	Continuous leakage
N39.46	Mixed incontinence
R32	Unspecified urinary incontinence
R35.0-R35.8	Polyuria
R39.15	Urgency of urination
R39.81	Functional urinary incontinence

Reviews, Revisions, and Approvals	Date	Approval Date
Converted corporate to local policy.	08/15/2020	

References

1. National Institute for Health and Care Excellence (NICE). Percutaneous posterior tibial nerve stimulation for overactive bladder syndrome, interventional procedures guidance [IPG362] Oct, 2010.
2. Gormley EA, Lightner DJ, Burgio KL, et al. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU Guideline Algorithm. Amended 2019. Available at: http://www.auanet.org/guidelines/overactive-bladder-(oab)-(aua/sufu-guideline-2012-amended-2014)
3. MacDiarmid SA, Peters KM, Shobeiri SA, et al. Long-term durability of percutaneous tibial nerve stimulation for the treatment of overactive bladder. J Urol. 2010 Jan;183(1):234-40.
4. Peters KM, Carrico DJ, MacDiarmid SA, et al. Sustained Therapeutic Effects of Percutaneous Tibial Nerve Stimulation: 24-month Results of the STEP Study. Neurourology and Urodynamics. 2012 Wiley Periodicals, Inc.
5. Blue Cross Blue Shield Technology Evaluation Center (BCBS TEC). Percutaneous Tibial Nerve Stimulation for the Treatment of Voiding Dysfunction. Volume 28, No. 10. January 2014.
6. 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 Nov 25;13:61.
7. van der Pal F, van Balken MR, Heesakkers JP, et al. Correlation between quality of life and voiding variables in patients treated with percutaneous tibial nerve stimulation. BJU Int. 2006 Jan;97(1):113-6.
8. Peters KM, Macdiarmid SA, Wooldridge LS, et al. Randomized trial of percutaneous tibial nerve stimulation versus extended-release tolterodine: results from the overactive bladder innovative therapy trial. J Urol. 2009 Sep;182(3):1055-61.
9. Ammi M, Chautard D, Brassart E, et al. Transcutaneous posterior tibial nerve stimulation: evaluation of a therapeutic option in the management of anticholinergic refractory overactive bladder. Int Urogynecol J. 2014 Aug;25(8):1065-9.
10. Vecchioli-Scaldazza C, Morosetti C, Berouz A, et al. Solifenacin succinate versus percutaneous tibial nerve stimulation in women with overactive bladder syndrome: results of a randomized controlled crossover study. Gynecol Obstet Invest. 2013;75(4):230-4.

11. Yoong W, Shah P, Dadswell R, et al. Sustained effectiveness of percutaneous tibial nerve stimulation for overactive bladder syndrome: 2-year follow-up of positive responders. Int Urogynecol J. 2012 Sep 7
12. National Institute for Health and Care Excellence (NICE). Urinary incontinence in women: management. Clinical guideline [CG171] Published date: September 2013 Last updated: November 2015
13. Johnson TM. Nocturia: Clinical presentation, evaluation, and management in adults. In: UpToDate. O'Leary MP (Ed), UpToDate, Waltham MA. Accessed July 21, 2020.
14. Lukacz ES. Treatment of urgency incontinence/overactive bladder in women. In: UpToDate. Brubaker L, Schmader KE. (Eds). UpToDate, Waltham MA. Accessed July 20, 2020.
15. van Breda HMK, Martens FMJ, Tromp J, Heesakkers JPFA. A New Implanted Posterior Tibial Nerve Stimulator for the Treatment of Overactive Bladder Syndrome: 3-Month Results of a Novel Therapy at a Single Center. J Urol. 2017 Jul;198(1):205-210
16. Del Río-Gonzalez S, Aragon IM, Castillo E, et al. Percutaneous Tibial Nerve Stimulation Therapy for Overactive Bladder Syndrome: Clinical Effectiveness, Urodynamic, and Durability Evaluation. Urology. 2017 Oct;108:52-58
17. Hayes Health Technology Assessment. Percutaneous Tibial Nerve Stimulation For The Treatment Of Symptomatic Neurogenic Lower Urinary Tract Dysfunction. April 15, 2019. Accessed July 20, 2020.
18. Hayes Comparative Effectiveness Review of Percutaneous Tibial Nerve Stimulation For the Treatment of Symptomatic Non-Neurogenic Overative Bladder. October 31, 2018. Accessed July 20, 2020.
19. Yamashiro J, de Riese W, de Riese, C. New Implantable Tibial Nerve Stimulation Devices: Review of Published Clinical Results in Comparison to Established Neuromodulation Devices. Res Rep Urol. 2019; 11:351-357. Published 2019 Dec 23. doi: 10.2147/RRU.S231954

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy,

contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

This clinical policy is the property of LHCC. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

©2020 Louisiana Healthcare Connections. All rights reserved. All materials are exclusively owned by Louisiana Healthcare Connections and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Louisiana Healthcare Connections. You may not alter or remove any trademark, copyright or other notice contained herein. Louisiana Healthcare Connections is a registered trademark exclusively owned by Louisiana Healthcare Connections.