Clinical Policy: Posterior Tibial Nerve Stimulation for Voiding Dysfunction

Reference Number: CP.MP.133 Coding Implications
Date of Last Revision: 08/22 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.[1] This policy describes the medical necessity requirements for posterior tibial nerve stimulation.

Policy/Criteria

I. It is the policy of health plans affiliated with Centene Corporation® that posterior tibial nerve stimulation (PTNS) is **medically necessary** for the treatment of moderate to severe urinary dysfunction and overactive bladder (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/enrollee's ability to participate in activities of daily living);
B. There has been a failure of, contraindications to, or intolerance to conservative medical management (e.g. behavioral therapies such as bladder training or pelvic floor muscle training and pharmacotherapy with oral anti-muscarinics or β3-adrenoceptor agonists and/or antibiotics for urinary tract infections);
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 health plans affiliated with Centene Corporation 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 health plans affiliated with Centene Corporation that there is insufficient evidence to support the use of PTNS beyond 12 months or when there is no improvement in urinary dysfunction.

IV. It is the policy of health plans affiliated with Centene Corporation that there is insufficient evidence in the published peer-reviewed literature to support the use of implantable tibial nerve stimulation for the treatment of urinary voiding dysfunction.

Background

The term “voiding dysfunction" has been used to refer to urinary incontinence, urinary retention, and symptoms of frequency and urgency. Overactive bladder (OAB) is a specific type of voiding dysfunction that includes any of the following symptoms: urinary frequency, urinary urgency, urge incontinence, and nocturia.[2] 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.[3-4]

Posterior tibial nerve stimulation (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.[5]

Several implantable tibial nerve neuromodulation systems, including a battery-less leadless, miniature implantable device, are currently under investigation for the management of OAB, however, evidence is still limited on their benefits and efficacy at this time.

National Institute for Health and Care Excellence (NICE)
According to NICE, current evidence demonstrates that PTNS for OAB syndrome is effective in reducing symptoms in the short term and medium term. Per NICE guidance, PTNS for OAB syndrome does not have major safety concerns, and the use of this procedure should with standard protocols for consent, audit, and clinical governance.[3]

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.[11]

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 minutes of stimulation once a week for 12 weeks (the trial duration; for continued benefit, weekly stimulation would have to continue).[1]

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.[6] 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.[7]

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
N39.45	Continuous leakage
N39.46	Mixed incontinence
R32	Unspecified urinary incontinence
R35.0 through R35.8	Polyuria
R39.15	Urgency of urination
R39.81	Functional urinary incontinence

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy adopted from Health Net NMP368 Posterior Tibial Nerve Stimulation for Voiding Dysfunction	10/16	10/16
References reviewed and updated.	09/17	10/17
Background updated. References reviewed and updated.	07/18	08/18
Revised I.B, examples of pharmacotherapy, to include oral anti-muscarinics or β3-adrenoceptor agonists. References reviewed and updated. Specialist review.	07/19	08/19
Added to the policy criteria that implantable tibial nerve stimulation is investigational. Added the following CPT codes as investigational: 0587T, 0588T,0589T and 0590T	01/20	02/20
References reviewed and updated.	07/20	08/20
Annual review. Replaced "investigational" language with "insufficient evidence to support." References reviewed, reformatted and updated. Changed "review date" in the header to "date of last revision" and "date" in the revision log header to "revision date." Replaced member with member/enrollee. Specialist review.	08/21	08/21
Annual review. Revised Criteria I.B. to include examples of behavioral therapies such as bladder training or pelvic floor muscle training. Background updated to with no impact on criteria. Dashes removed from code ranges. References reviewed and updated.	08/22	08/22

References

1. Lightner DJ, Gomelsky A, Souter L, Vasavada SP. Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults: AUA/SUFU Guideline Amendment 2019. *J Urol*. 2019;202(3):558 to 563. doi:10.1097/JU.0000000000000309
2. Lukacz ES. Urgency urinary incontinence/overactive bladder (OAB) in females: Treatment. UpToDate. www.uptodate.com. Published September 24, 2021. Accessed July 07, 2022.

3. National Institute for Health and Care Excellence. Percutaneous posterior tibial nerve stimulation for overactive bladder syndrome - Interventional procedures guidance [IPG362]. https://www.nice.org.uk/guidance/ipg362. Published October 2010. Accessed July 08, 2022.
4. Local coverage determination: posterior tibial nerve stimulation (PTNS) (L33406). Centers for Medicare and Medicaid Services Web site. http://www.cms.hhs.gov/mcd/search.asp. Published October 01, 2015 (revised January 08, 2019). Accessed July 13, 2022.
5. Health Technology Assessment. Comparative effectiveness review of percutaneous tibial nerve stimulation for the treatment of symptomatic non-neurogenic overactive bladder. Hayes. www.hayesinc.com. Published October 31, 2018 (annual review November 08, 2021) Accessed July 07, 2022.
6. 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;183(1):234 to 240. doi:10.1016/j.juro.2009.08.160
7. Peters KM, Carrico DJ, MacDiarmid SA, et al. Sustained therapeutic effects of percutaneous tibial nerve stimulation: 24-month results of the STEP Study. *Neurourol Urodyn.* 2013;32(1):24 to 29. doi:10.1002/nau.22266
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;182(3):1055 to 1061. doi:10.1016/j.juro.2009.05.045
9. Ammi M, Chautard D, Brassart E, Culty T, Azzouzi AR, Bigot P. Transcutaneous posterior tibial nerve stimulation: evaluation of a therapeutic option in the management of anticholinergic refractory overactive bladder. *Int Urogynecol J*. 2014;25(8):1065 to 1069. doi:10.1007/s00192-014-2359-0
10. Yoong W, Shah P, Dadswell R, Green L. Sustained effectiveness of percutaneous tibial nerve stimulation for overactive bladder syndrome: 2-year follow-up of positive responders. *Int Urogynecol J*. 2013;24(5):795 to 799. doi:10.1007/s00192-012-1936-3
11. National Institute for Health and Care Excellence. Urinary incontinence and pelvic organ prolapse in women: management - NICE guideline [NG123]. https://www.nice.org.uk/guidance/ng123. Published April 02, 2019. (Last updated June 24, 2019). Accessed July 11, 2022.
12. Johnson TM. Nocturia: Clinical presentation, evaluation, and management in adults. UpToDate. www.uptodate.com. Published January 12, 2021. Accessed July 07, 2022.
13. Blue Cross Blue Shield; Kaiser Foundation Health Plan; Southern California Permanente Medical Group. Percutaneous tibial nerve stimulation for the treatment of voiding dysfunction. *Technol Eval Cent Assess Program Exec Summ*. 2014;28(10):1 to 12.
14. 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;198(1):205 to 210. doi:10.1016/j.juro.2017.01.078
15. 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;108:52 to 58. doi:10.1016/j.urology.2017.04.059
16. Health Technology Assessment. Percutaneous tibial nerve stimulation for the treatment of symptomatic neurogenic lower urinary tract dysfunction. Hayes. www.hayesinc.com. Published April 15, 2019 (annual review April 01, 2022) Accessed July 12, 2022.

17. 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. Published 2013 Nov 25. doi:10.1186/1471-2490-13-61
18. 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 to 357. Published 2019 Dec 23. doi: 10.2147/RRU.S231954
19. Vecchioli-Scaldazza C, Morosetti C, Berouz A, Giannubilo W, Ferrara V. 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 to 234. doi:10.1159/000350216
20. van der Pal F, van Balken MR, Heesakkers JP, Debruyne FM, Kiemeney LA, Bemelmans BL. Correlation between quality of life and voiding variables in patients treated with percutaneous tibial nerve stimulation. *BJU Int.* 2006;97(1):113 to 116. doi:10.1111/j.1464-410X.2006.05860.x

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. The Health Plan 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. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. 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. The Health Plan 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 member/enrollees. This clinical policy is not intended to recommend treatment for member/enrollees. Member/enrollees 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 the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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

Note: For Medicaid member/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare member/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.