Clinical Policy: Posterior Tibial Nerve Stimulation for Voiding Dysfunction

Reference Number: CP.MP.133
Date of Last Revision: 08/23
Effective Date: 10/01/23

Coding Implications
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 when all of the following criteria are met:
   A. Diagnosis of overactive bladder;
   B. There has been a failure of conservative medical management (e.g. behavioral therapies such as bladder training or pelvic floor muscle training, or pharmacotherapy with oral anti-muscarinics or β3-adrenoceptor agonists and/or antibiotics for urinary tract infections) unless conservative management is not desired or is medically contraindicated;
   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]

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 five centimeters (cm) cephalad to the medial malleolus and two 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 nine 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 six to eight sessions. Maintenance treatment sessions may be required to sustain the response to treatment.[4]

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.[10]

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 six to12 months reported excellent durability through 12 months.[5] 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.[6]

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 2022, 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

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
Annual review. Revised policy statement and all criteria verbiage in criteria I. ICD-10 CM Diagnosis Code table removed. References reviewed and updated. Reviewed by external specialist.	08/23	

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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.

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.