

Corporate Medical Policy

Posterior Tibial Nerve Stimulation for Voiding Dysfunction

File Name: posterior_tibial_nerve_stimulation_for_voiding_dysfunction
Origination: 1/2007
Last CAP Review: 11/2011
Next CAP Review: 11/2012
Last Review: 11/2011

Description of Procedure or Service

Posterior tibial nerve stimulation (PTNS) is a technique of electrical stimulation for the treatment of voiding dysfunction in patients who have failed behavioral therapies and/or pharmacologic therapies. Voiding dysfunction includes urinary frequency, urgency, incontinence and nonobstructive retention. Common causes of voiding dysfunction are pelvic floor dysfunction (from pregnancy, childbirth, surgery, etc.), inflammation, medication side effects (e.g., diuretics and anticholinergics), obesity, psychogenic factors and disease (e.g., multiple sclerosis, spinal cord injury, detrusor hyperreflexia, diabetes with peripheral nerve involvement, etc.). Altering the function of the posterior tibial nerve with PTNS is believed to improve voiding function and control. While the posterior tibial nerve is located near the ankle, it is derived from the lumbar-sacral nerves (L4-S3) which control the bladder detrusor and perineal floor.

The system used to provide PTNS consists of a small gauge needle electrode, surface electrode, lead wire, and handheld electrical generator. The percutaneous needle is inserted into the ankle. After the lead wire and electrode are attached, the stimulator is turned on and the amplitude is slowly increased until the patient's response indicates proximity to the nerve bundle (i.e., the large toe starts to curl, the toe digits fan out, or the entire foot extends.) Noninvasive PTNS has also been delivered with surface electrodes. PTNS studies have been designed as 30-minute sessions given weekly for 10-12 weeks. Recently, consideration has been given to increasing the frequency of treatments to 3 times per week to speed achievement of desired outcomes. However, an optimal treatment approach has not been identified and the durability of PTNS is uncertain.

PTNS must be distinguished from acupuncture with electrical stimulation. In electrical acupuncture, needles are also inserted just below the skin, but the placement of needles is based on specific theories regarding energy flow throughout the human body. Thus in PTNS, the location of stimulation is directly in the posterior tibial nerve rather than using the theories of energy flow that guide placement of stimulation for acupuncture.

In July 2005, the Urgent® PC Neuromodulation System (Uroplasty, Inc.) received 510(k) marketing clearance for percutaneous tibial nerve stimulation to treat patients suffering from urinary urgency, urinary frequency and urge incontinence. This device was cleared as a class II "nonimplanted, peripheral nerve stimulator for pelvic floor dysfunction" because it was considered to be substantially equivalent to the previously cleared percutaneous Stoller afferent nerve system (PerQ SANS System) in 2001.

PTNS was derived as a less-invasive treatment alternative to traditional sacral root neuromodulation which has been successfully used in the treatment of urinary dysfunction, but requires implantation of a permanent device. In sacral root neuromodulation, an implantable pulse generator that delivers controlled electrical impulses is attached to wire leads that connect to the sacral nerves, most commonly the S3 nerve root that modulates the neural pathways controlling bladder function.

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****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.*

Policy

BCBSNC will not provide coverage for posterior tibial nerve stimulation for urinary dysfunction, including but not limited to overactive bladder syndrome, urinary frequency, urgency, incontinence and retention, because it is considered investigational. BCBSNC does not cover investigational services.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Posterior Tibial Nerve Stimulation for Voiding Dysfunction is covered

Not Applicable

When Posterior Tibial Nerve Stimulation for Voiding Dysfunction is not covered

Posterior tibial nerve stimulation for voiding dysfunction, including but not limited to overactive bladder syndrome, urinary frequency, urgency, incontinence and retention, is not covered. It is considered investigational and BCBSNC does not cover investigational services.

Policy Guidelines

Posterior tibial nerve stimulation (PTNS) is a technique of electrical neuromodulation used for treating voiding dysfunction. The available trials report short-term improvements on measures of urinary incontinence, but the long-term effectiveness and the need for a maintenance regimen are poorly defined. Until the durability of percutaneous tibial nerve stimulation has been demonstrated in well-designed longterm comparative studies and its clinical impact more clearly shown, its efficacy for treating chronic urinary dysfunction remains uncertain.

The 2005 American College of Obstetricians and Gynecologists practice bulletin on treatment of urinary incontinence in women does not address PTNS or other types of nerve stimulation.

The American Urological Association guideline for treatment of stress incontinence does not address PTNS for treatment of overactive bladder syndrome, urgency frequency or urge incontinence.

A BCBSA TEC Assessment on PTNS for treatment of voiding dysfunction was completed in December 2010. The Assessment reviewed the published RCTs and concluded that PTNS as treatment for voiding dysfunction does not meet the TEC criteria due to insufficient data on durability of treatment. The Assessment stated that, although there is sufficient evidence from 3 RCTs to establish a short-term benefit for PTNS, the evidence is not sufficient to permit conclusions on the long-term efficacy of PTNS treatment.

Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 64566

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

External Specialty Matched Consultant review 4/4/06

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.106, 7/20/06.

Specialty Matched Consultant Advisory Panel review 5/8/07.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.106, 9/18/07.

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.106, 10/07/08.

Nuhoglu B, Fidan V, Ayyildiz A et al. Stoller afferent nerve stimulation in woman with therapy resistant over active bladder; a 1-year follow up. *Int Urogynecol J Pelvic Floor Dysfunct* 2006; 17(3):204-7.

van der Pal F, van Balken MR, Heesakkers JP et al. Percutaneous tibial nerve stimulation in the treatment of refractory overactive bladder syndrome: is maintenance treatment necessary? *BJU Int* 2006; 97(3):547-50.

Finazzi Agro E, Campagna A, Sciobica F et al. Posterior tibial nerve stimulation: is the once-a-week protocol the best option? *Minerva Urol Nefrol* 2005; 57(2):119-23.

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; 97(1):113-6.

Kim SW, Paick JS, Ku JH. Percutaneous posterior tibial nerve stimulation in patients with chronic pelvic pain: a preliminary study. *Urol Int* 2007; 78(1):58-62.

Specialty Matched Consultant Advisory Panel review - 9/2009

American College of Obstetricians and Gynecologists (ACOG). Urinary incontinence in women. ACOG Practice Bulletin, no. 63. Retrieved on November 8, 2010 from www.guideline.gov.

American Urological Association Education and Research. Guideline for the surgical management of female stress urinary incontinence: 2009 update. Retrieved on November 8, 2010 from www.guideline.gov.

National Institutes of Health (NIH). Study of Urgent PC Versus Sham Effectiveness in Treatment of Overactive Bladder Symptoms (SUMiT). Identifier number NCT00771264. Retrieved on November 8, 2010 from <http://www.clinicaltrials.gov/ct2/show/NCT00771264>

National Institutes of Health (NIH). Modified Extension Study to the SUMiT Trial: Evaluation of Long Term Therapy With Percutaneous Tibial Nerve Stimulation (PTNS) for Overactive Bladder

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Symptoms (STEP). Identifier number NCT00928395. Retrieved on November 8, 2010 from <http://www.clinicaltrials.gov/ct2/show/NCT00928395>

Specialty Matched Consultant Advisory Panel review 12/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.106, 10/8/10

Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Percutaneous tibial nerve stimulation for the treatment of voiding dysfunction. [Electronic Version]. December 2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.106, 1/13/11

Specialty Matched Consultant Advisory Panel review 11/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.106, 1/12/12

Policy Implementation/Update Information

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| 1/3/07 | Notification of new policy. BCBSNC will not provide coverage for posterior tibial nerve stimulation for urinary dysfunction, including but not limited to urinary frequency, urgency, incontinence and retention, because it is considered investigational. BCBSNC does not cover investigational services. Notification given 1/3/07. Effective date 3/12/07. (pmo) |
| 6/4/07 | Specialty Matched Consultant Advisory Panel review 5/8/07. No changes to criteria. Reference source added. (pmo) |
| 9/28/09 | No changes to criteria. Repeated same types of urinary dysfunction under "When not Covered" that is included in policy statement. Reference sources added. (pmo) |
| 6/22/10 | Policy Number(s) removed (amw) |
| 1/18/11 | Specialty Matched Consultant Advisory Panel review 12/2010. Policy Guidelines updated. References updated. Added CPT code 64566 and deleted CPT code 64999. Added "overactive bladder syndrome" to the Policy statement as well as to the "When not covered" section. (mco) |
| 12/20/11 | Specialty Matched Consultant Advisory Panel review 11/2011. References updated. BCBSA 2010 TEC Assessment information added to Policy Guidelines. No changes to Policy Statement. (mco) |
| 3/20/12 | References updated. Policy Guidelines updated. No changes to policy statement. (mco) |

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.