

Contractor Name

Wisconsin Physicians Service (WPS)

Contractor Number

00951, 00952, 00953, 00954

05101, 05201, 05301, 05401, 05102, 05202, 05392, 05302, 05402

Contractor Type

Carrier

MAC A

MAC B

LCD Database ID Number

Wisconsin

Illinois

Michigan

Minnesota

Iowa

Kansas

Missouri

Nebraska

LCD Version Number**LCD Title**

Posterior tibial nerve stimulation (PTNS)

Contractor's Determination Number

GSURG-043

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CMS National Coverage Policy

CMS Publication 100-04 Medicare Claims Processing Manual

Primary Geographic Jurisdiction

Wisconsin

Illinois

Michigan

Minnesota

Iowa

Kansas

E Missouri

W Missouri

Nebraska

Oversight Region

Region I
Region V

CMS Consortium

Midwest
Northwestern

Original Determination Effective Date

Wisconsin:
Illinois:
Michigan:
Minnesota:
Iowa
Kansas
Missouri
Nebraska

Revision Effective Date

Pending

CMS Consortium

Midwest

Original Determination Effective Date**Revision Effective Date****Indications and Limitations of Coverage and/or Medical Necessity**

Posterior tibial nerve stimulation for urinary dysfunction, including but not limited to urinary frequency, urgency, incontinence and retention, is considered investigational and is not covered under Medicare. Services billed to Medicare will be denied as not medically necessary.

Posterior tibial nerve stimulation (PTNS) is a technique of electrical neuromodulation for the treatment of voiding dysfunction in patients who have failed behavioral 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 (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 procedure for PTNS consists of the insertion of a needle above the medial malleolus into the posterior tibial nerve followed by the application of low voltage (10mA, 1–10 Hz frequency) electrical stimulation that produces sensory and motor responses (i.e., a tickling sensation and plantar flexion or fanning of all toes). Noninvasive PTNS has also been delivered with surface electrodes. PTNS studies have reported on 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 (see policy No. 7.01.01). 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 (K992069, UroSurge, Inc.).

PTNS was developed 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.

Note: Stimulation of the sacral nerve as a treatment of incontinence is discussed separately in policy No. 7.01.69. Pelvic floor stimulation as a treatment of urinary incontinence refers to electrical stimulation of the pudendal nerve and is addressed separately in policy No. 1.01.17.

State or federal mandates (e.g., FEP) may dictate that all devices approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational. Therefore, FDA-approved devices may be assessed on the basis of their medical necessity.

Study selection criteria used in the 1996 TEC Assessment on percutaneous electrical nerve stimulation (PENS) can be applied for the evaluation of evidence on PTNS:

- the study contained original empirical data;
- the study design included a treatment group and a control group;
- the study reported on a health outcome relevant to the condition treated; and
- the study used a random assignment, control group design.

The literature search revealed no randomized trials meeting the above criteria. Evidence from clinical series tends to overestimate treatment effect. These studies do not account for placebo effects or for dropouts by using intent-to-treat analysis. Randomized controlled clinical trials are needed to control for the effects of bias and to demonstrate the efficacy of PTNS.

Several clinical studies have reported on the use of PTNS with some favorable outcomes, including reductions in urinary frequency and urgency. However, no randomized, controlled trials have been published comparing PTNS to placebo or other voiding dysfunction treatments. In a prospective observational study, Nuhoglu et al. treated 35 patients with overactive bladder with 10 weekly 30-minute sessions using the UroSurge device. (1) Nineteen patients (54%) experienced significant reductions in urinary urgency and increases in urine volume after therapy.

However, these effects were maintained in only 8 patients (23%) after 1 year. In a small study of 11 patients, van der Pal and colleagues also found limited durability of PTNS treatment effects as increases in incontinence and/or voiding frequency occurred in 50% or more patients 6 weeks after treatment. (2) When treatment was resumed, the incontinence and/or voiding frequency decreased 50% or more. While these studies are small, the effects of PTNS appear to be short term. And as the van der Pal authors indicate, continuous PTNS may be necessary. Finally, Finazzi and colleagues found no differences in outcomes in 35 patients randomized to PTNS weekly versus 3 times per week. (3) The authors noted patients in both treatment groups had subjective improvements after 6–8 sessions of PTNS suggesting more frequent treatment initially may result in earlier achievement of desired effects even though the frequency of PTNS did not influence the final outcomes in this study.

In conclusion, randomized trials with appropriate control groups are needed to determine the durability and short- and long-term effects of PTNS on voiding dysfunction. Additionally, further randomized trials to determine appropriate treatment periodicity are needed.

Note: There is no separate policy statement for patients with interstitial cystitis, as they would be considered candidates for PTNS therapy based on the presence of urgency and frequency alone.

A search of the MEDLINE database for the period of July 2006 through July 2007 did not identify any studies that would alter the conclusions reached above. Van der Pal and colleagues published an analysis of quality of life questionnaires from 29 patients who were treated with PTNS (3 times/week for 4 weeks) for urge urinary incontinence (4) Information from Figure 1 of the article indicates that at least 12 of the subjects had either no change or an increase in the number of pads used. The authors report that they are currently conducting a randomized double-blind placebo-controlled trial. Another study assessed the efficacy of 12 weeks (1 time/week) of PTNS in 15 patients with chronic pelvic pain in an open prospective clinical trial. (5) The study found subjective improvements in VAS pain scores (8.1 to 4.1) and VAS urgency (4.5 to 2.7), with no change in the number of voids or bladder volume. Since these subjective improvements may be due to placebo, double-blinded controlled trials are needed. In addition, since questions remain about the long-term efficacy of PTNS, longer follow-up will be needed to evaluate this procedure.

Coverage Topic

Surgery

CPT/HCPCS Codes

64999	Unlisted procedure, nervous system
97014	Application of a modality to one or more areas; electrical stimulation (unattended)
97032	Application of a modality to one or more areas; electrical stimulation (manual), each 15 minutes

Does the CPT 30% Rule Apply

No

ICD-9 Codes that Support Medical Necessity

Note: ICD-9 codes must be coded to the highest level of specificity.

86.09	Other incision of skin and subcutaneous tissue
788.20–	Retention of urine code range

788.29

788.31 Urge incontinence (the underlying condition must be coded first followed by this code)

Diagnoses that Support Medical Necessity

See ICD-9 listed above

ICD-9 Codes that DO NOT Support Medical Necessity

ICD-9 codes not listed in this policy

Diagnoses that DO NOT Support Medical Necessity

Diagnoses not listed in this policy

Documentation Requirements

The correct CPT code to use for PTNS is the unlisted CPT code 64999. CPT codes for percutaneous implantation of neurostimulator electrodes (i.e., 64553-64565) are not appropriate since PTNS uses percutaneously inserted needles and wires rather than percutaneously implanted electrodes. The stimulation devices used in PTNS and PNT are not implanted, so CPT code 64590 is also not appropriate.

Services provided as components to non-covered services are also not covered.

Utilization Guidelines

NA

Sources of Information and Basis for Decision

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.

Advisory Committee Meeting Notes

Meeting Date:

Wisconsin: 9/26/2008

Illinois: 9/17/2008

Michigan: 9/24/2008

Minnesota: 9/11/2008

MAC J-5 October

Start Date of Comment Period

Wisconsin:

Illinois:

Michigan:
Minnesota:
MAC J-5

End Date of Comment Period

Wisconsin:
Illinois:
Michigan:
Minnesota:
MAC-J5

Start Date of Notice Period

(Published)

Revision History

Last Reviewed On

Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from the Illinois, Michigan, Wisconsin and Minnesota Psychiatric Society.

* - An asterisk indicates a revision to that section of the policy.

Does this LCD contain a "Least Costly Alternative" Provision?

No