



# Medical Policy

Policy: 201318

Initial Effective Date: 11/22/2013

SUBJECT: Percutaneous Tibial Nerve Stimulation

Annual Review Date: 04/25/2018

Last Revised Date: 04/25/2018

**Prior approval is required for some or all procedure codes listed in this Corporate Medical Policy.**

**Definition:** Percutaneous tibial nerve stimulation (PTNS) (Urgent® PC Neuromodulation System, Uroplasty, Inc., Minneapolis, MN) involves minimally invasive neurostimulation proposed as a neuromodulation treatment for overactive bladder or urinary bladder dysfunction (e.g., urinary frequency<sup>†</sup>, urgency<sup>††</sup>, urge incontinence), chronic pelvic floor pain and fecal incontinence. A fine needle is inserted percutaneously cephalad and medial to the ankle to access the posterior tibial nerve and a small surface electrode is placed over the medial calcaneus on the same leg. The needle and electrode are connected to a low-voltage stimulator, which produces variable, retrograde sacral nerve plexus stimulation via the tibial nerve.

**Medical Necessity:** The Company considers percutaneous tibial nerve stimulation (**CPT Code 64566**) **medically necessary** and eligible for reimbursement providing that *all* of the following medical criteria are met:

- Age  $\geq$ 18 years; and
- Established diagnosis of overactive bladder (urinary frequency<sup>†</sup>, urgency<sup>††</sup> or urge incontinence) unresponsive to conventional medical therapy including all of the following:
  1. No significant improvement despite compliance with behavioral therapy (at least two modalities - e.g., pelvic floor exercises, bladder control strategies, timed voids, fluid management); and
  2. Failure of, intolerance to or unable to receive conventional pharmacologic therapy (at least two different anti-muscarinic agents or a combination of anti-muscarinic and tricyclic antidepressant therapy); and
- Documented symptoms ( $\geq$ 1 year) of urinary frequency<sup>†</sup>, urgency<sup>††</sup> or urge incontinence resulting in significant disability<sup>†††</sup>; and
- Adequate bladder capacity and anatomically normal urinary tract; and
- Active urinary tract infection and other disorders that could be the cause of the symptoms have been excluded;



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**Frequency limitations:** The Company limits the frequency of percutaneous tibial nerve stimulation to one 30 minute treatment every seven days for a period of 12 consecutive weeks. Requests for maintenance therapy or retreatment will be considered on a case by case basis providing significant, objective improvement has occurred based upon voiding diaries (voids/24 hours, nocturnal voids, moderate to severe urgency episodes) and patient compliance has been established.

The Company considers percutaneous tibial nerve stimulation **investigational** and **not** eligible for reimbursement for **all** other clinical conditions including, but not limited to, the following:

- Nocturia; and
- Nonobstructive urinary retention; and
- Interstitial cystitis; and
- Neurogenic lower urinary tract dysfunction; and
- Chronic pelvic floor pain; and
- Fecal incontinence.

**†Urinary frequency:** The Company defines urinary frequency as  $\geq 8$  voids per day, causing disruption in activities of daily living.

**††Urinary urgency:** The Company defines urinary urgency as the intense need to void (with or without accompanying urinary incontinence), causing disruption in activities of daily living.

**†††Disability:** The Company defines disability as severe urinary frequency, urgency or urge incontinence symptoms, which significantly limit ability to work or participate in activities outside the home. Documentation by the provider must be included to demonstrate the nature and severity of the disability.

### **Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

**Prior approval is required for CPT Code 64566.**



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**Sources of Information:**

- Agency for Healthcare Research and Quality. National Guideline Clearinghouse. (2014, May). *Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU guideline*. Retrieved from <http://www.guideline.gov/content.aspx?id=48226>.
- Hayes, Inc. (2014, December 09). *Percutaneous tibial nerve stimulation for the treatment of lower urinary tract dysfunction*. Annual Review (2016, November 15).Lansdale, PA: Author.
- MacDiarmid, S.A., Peters, K.M., Shobeiri, S.A., Wooldridge, L.S., Rovner, E.S., Leong, F.C., ... Feagins, B.A. (2010). Long-term durability of percutaneous tibial nerve stimulation for the treatment of overactive bladder. *J Urol*, 183(1):234-240.
- National Institute for Health and Clinical Excellence. (2013, September). *Urinary incontinence: the management of urinary incontinence in women*. Retrieved from <http://www.guideline.gov/content.aspx?id=47099>.

<b>Applicable Code(s):</b>	
<b>CPT:</b>	<b>64566</b>
<b>HCPCS:</b>	<b>NA</b>
<b>ICD10 Procedure Codes:</b>	<b>NA</b>

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