FEP 7.01.106 Percutaneous Tibial Nerve Stimulation

Effective Date: July 15, 2018

Related Policies: 1.01.17 Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence
2.01.58 Transanal Radiofrequency Treatment of Fecal Incontinence
7.01.19 Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence
7.01.29 Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy

Percutaneous Tibial Nerve Stimulation

Description

Percutaneous tibial nerve stimulation (PTNS; also known as posterior tibial nerve stimulation) is a technique of electrical neuromodulation used primarily for treating voiding dysfunction.

FDA REGULATORY STATUS

In July 2005, the Urgent® PC Neuromodulation System was the initial device cleared for marketing by FDA through the 510(k) process for PTNS to treat patients suffering from urinary urgency, urinary frequency, and urge incontinence. Additional percutaneous tibial nerve stimulators have been cleared for marketing through the 510(k) process. They are listed in Table 1.

The Urgent® PC Neuromodulation System and NURO™ Neuromodulation System are not FDA-cleared for other indications, such as the treatment of fecal incontinence.

There is developing wireless technology for the treatment of overactive bladder, approved in Europe. BlueWind (BlueWind Medical) is a wireless, battery-less, miniature implantable neurostimulator that is activated by an external device worn at the ankle.

Table 1 FDA-Cleared Percutaneous Tibial Nerve Stimulators (FDA Product Code: NAM)

Device Name	Manufacturer	Cleared	510(k)	Indications
Urgent® PC Neuromodulation System	Uroplasty, now Cogentix Medical	Oct 2005	K052025	Indicated for treatment of urinary urgency, urinary frequency, and urge incontinence
Urgent® PC Neuromodulation System	Uroplasty, now Cogentix Medical	Jul 2006	K061333	FDA determined the 70% isopropyl alcohol prep pad contained in the kit is subject to regulation as a drug
Urgent® PC Neuromodulation System	Uroplasty, now Cogentix Medical	Aug 2007	K071822	Labeling update, intended use is unchanged
Urgent® PC Neuromodulation System	Uroplasty, now Cogentix Medical	Oct 2010	K101847	Intended use statement adds the diagnosis of overactive bladder
NURO™ Neuromodulation System	Advanced Uro-Solutions, now Medtronic	Nov 2013	K132561	Intended to treat patients with overactive bladder and associated symptoms of urinary urgency, urinary frequency, and urge incontinence

FDA: Food and Drug Administration.

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POLICY STATEMENT

Percutaneous tibial nerve stimulation for an initial 12-week course is considered **medically necessary** for individuals with non-neurogenic urinary dysfunction including overactive bladder who have both:

- failed behavioral therapy following an appropriate duration of 8 to 12 weeks without meeting treatment goals; and
- failed pharmacologic therapy following 4 to 8 weeks of treatment without meeting treatment goals.

Maintenance therapy using monthly percutaneous tibial nerve stimulation is considered **medically necessary** for individuals following a 12-week initial course of percutaneous tibial nerve stimulation that resulted in improved urinary dysfunction meeting treatment goals.

Percutaneous tibial nerve stimulation is considered **investigationa**l for all other indications, including but not limited to the following:

- Neurogenic bladder dysfunction
- Fecal incontinence.

POLICY GUIDELINES

Patients may be considered to have failed behavioral therapies following an appropriate duration of 8 to 12 weeks without meeting treatment goals (Gormley et al [2015]).

Patients may be considered to have failed pharmacologic therapies following 4 to 8 weeks of treatment without meeting treatment goals (Gormley et al [2015]).

Annual evaluation by a physician may be performed to ensure efficacy is continuing for maintenance percutaneous tibial nerve stimulation treatments.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence

For individuals who have non-neurogenic urinary dysfunction including OAB who have failed behavioral and pharmacologic therapy who receive an initial course of PTNS, the evidence includes randomized sham-controlled trials, RCTs with an active comparator, and systematic reviews. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The SUmiT and the OrBIT trials are 2 key industry-sponsored RCTs. Systematic reviews that include these trials and other published trials have found short-term improvements with PTNS. The largest, highest quality study was the double-blinded, sham-controlled SUmiT trial. It reported a statistically significant benefit of PTNS vs sham at 12 weeks. In an additional small sham-controlled trial, a 50% reduction in urge incontinent episodes was attained in 71% of PTNS group compared with 0% in the sham group. The nonblinded OrBIT trial found that PTNS was noninferior to medication treatment at 12 weeks. Adverse events were limited to local irritation effects. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have OAB syndrome that has failed behavioral and pharmacologic therapy who respond to an initial course of PTNS who receive maintenance PTNS, the evidence includes observational studies and systematic reviews. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The SUmiT and the OrBIT trials each included extension studies that followed individuals who responded to the initial course of

PTNS and continued to receive periodic maintenance therapy. There is variability in the interval between and frequency of maintenance treatments, and an optimal maintenance regimen remains unclear. There are up to 36 months of observational data available, reporting that there is a durable effect for some of these patients. While comparative data are not available after the initial 12-week treatment period, the observational data support a clinically meaningful benefit for use in individuals who have already failed behavioral and pharmacologic therapy and who respond to the initial course of PTNS. PTNS may allow such individuals to avoid more invasive interventions. Adverse events appear to be limited to local irritation for both short and long-term PTNS use. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have neurogenic bladder dysfunction who receive PTNS, the evidence includes several RCTs and a systematic review of RCTs and observational data. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Only a few RCTs evaluating tibial nerve stimulation for treating neurogenic bladder have been published to date, and all but one performed transcutaneous stimulation rather than PTNS. Studies varied widely in factors, such as the study populations and comparison interventions. Study findings have not reported that tibial nerve stimulation significantly improved incontinence symptoms and other outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have fecal incontinence who receive PTNS, the evidence includes several RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The available RCTs have not found a clear benefit of PTNS. Neither of the sham-controlled trials found that active stimulation was superior to sham for achieving the primary outcome, at least a 50% reduction in mean weekly fecal incontinence episodes. The larger sham-controlled randomized trial did find a significantly greater decrease in the absolute number of weekly incontinence episodes in the active treatment group, but the overall trial findings did not suggest the superiority of PTNS over sham treatment. Systematic reviews have not conducted pooled analyses. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Urological Association et al

The American Urological Association and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (2015) published guidelines on the diagnosis and treatment of non-neurogenic overactive bladder in adults.[29] The guidelines included a statement that clinicians may offer percutaneous tibial nerve stimulation (PTNS) as a third-line treatment option in carefully selected patients. The statement carried a grade C rating, indicating that the balance of benefits and risks/burdens are uncertain. (This is a revised version of a 2012 guideline; the statement on PTNS did not change).

American College of Obstetricians and Gynecologists

The 2015 American College of Obstetricians and Gynecologists practice bulletin on the treatment of urinary incontinence in women did not address PTNS or other types of nerve stimulation.[30]

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Percutaneous tibial nerve stimulation for the treatment of voiding dysfunction. *TEC Assessments.* 2013;Volume 28:Tab 10.
2. Peters KM, Carrico DJ, Perez-Marrero RA, et al. Randomized trial of percutaneous tibial nerve stimulation versus Sham efficacy in the treatment of overactive bladder syndrome: results from the SUmiT trial. *J Urol.* Apr 2010;183(4):1438-1443. PMID 20171677
3. Peters K, Carrico D, Burks F. Validation of a sham for percutaneous tibial nerve stimulation (PTNS). *Neurourol Urodyn.* Jul 31 2009;28(1):58-61. PMID 18671297
4. Peters KM, Carrico DJ, Wooldridge LS, et al. Percutaneous tibial nerve stimulation for the long-term treatment of overactive bladder: 3-year results of the STEP study. *J Urol.* Jan 2013;189(6):2194-2201. PMID 23219541
5. Finazzi-Agro E, Petta F, Sciobica F, et al. Percutaneous tibial nerve stimulation effects on detrusor overactivity incontinence are not due to a placebo effect: a randomized, double-blind, placebo controlled trial. *J Urol.* Nov 2010;184(5):2001-2006. PMID 20850833
6. 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.* Sep 2009;182(3):1055-1061. PMID 19616802
7. MacDiarmid SA, Peters KM, Shobeiri SA, et al. Long-term durability of percutaneous tibial nerve stimulation for the treatment of overactive bladder. *J Urol.* Jan 2010;183(1):234-240. PMID 19913821
8. Boudaoud N, Binet A, Line A, et al. Management of refractory overactive bladder in children by transcutaneous posterior tibial nerve stimulation: A controlled study. *J Pediatr Urol.* Jun 2015;11(3):138 e131-110. PMID 25979217
9. Gungor Ugurlucan F, Onal M, Aslan E, et al. Comparison of the effects of electrical stimulation and posterior tibial nerve stimulation in the treatment of overactive bladder syndrome. *Gynecol Obstet Invest.* Nov 16 2013;75(1):46-52. PMID 23171636
10. Preyer O, Umek W, Laml T, et al. Percutaneous tibial nerve stimulation versus tolterodine for overactive bladder in women: a randomised controlled trial. *Eur J Obstet Gynecol Reprod Biol.* Aug 2015;191:51-56. PMID 26073262
11. Vecchioli-Scaldazza C, Morosetti C, Berouz A, et al. Solifenacin succinate versus percutaneous tibial nerve stimulation in women with overactive bladder syndrome: results of a randomized controlled crossover study. *Gynecol Obstet Invest.* Mar 28 2013;75(4):230-234. PMID 23548260
12. Schreiner L, dos Santos TG, Knorst MR, et al. Randomized trial of transcutaneous tibial nerve stimulation to treat urge urinary incontinence in older women. *Int Urogynecol J.* Sep 2010;21(9):1065-1070. PMID 20458465
13. Burton C, Sajja A, Latthe PM. Effectiveness of percutaneous posterior tibial nerve stimulation for overactive bladder: a systematic review and meta-analysis. *Neurourol Urodyn.* Nov 2012;31(8):1206-1216. PMID 22581511
14. Levin PJ, Wu JM, Kawasaki A, et al. The efficacy of posterior tibial nerve stimulation for the treatment of overactive bladder in women: a systematic review. *Int Urogynecol J.* Nov 2012;23(11):1591-1597. PMID 22411208
15. Moossdorff-Steinhauser HF, Berghmans B. Effects of percutaneous tibial nerve stimulation on adult patients with overactive bladder syndrome: A systematic review. *Neurourol Urodyn.* Mar 2013;32(3):206-214. PMID 22907807
16. 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.* Nov 25 2013;13:61. PMID 24274173
17. Shamliyan T, Wyman J, Kane RL. *Nonsurgical Treatments for Urinary Incontinence in Adult Women: Diagnosis and Comparative Effectiveness (Comparative Effectiveness Review No. 36).* Rockville, MD: Agency for Healthcare Research and Quality; 2012.
18. Stewart F, Gameiro LF, El Dib R, et al. Electrical stimulation with non-implanted electrodes for overactive bladder in adults. *Cochrane Database Syst Rev.* Dec 09 2016;12:Cd010098. PMID 27935011
19. Schneider MP, Gross T, Bachmann LM, et al. Tibial nerve stimulation for treating neurogenic lower urinary tract dysfunction: a systematic review. *Eur Urol.* Nov 2015;68(5):859-867. PMID 26194043
20. Monteiro ES, de Carvalho LB, Fukujima MM, et al. Electrical stimulation of the posterior tibialis nerve improves symptoms of poststroke neurogenic overactive bladder in men: a randomized controlled trial. *Urology.* Sep 2014;84(3):509-514. PMID 25168524
21. Perissinotto MC, D'Ancona CA, Lucio A, et al. Transcutaneous tibial nerve stimulation in the treatment of lower urinary tract symptoms and its impact on health-related quality of life in patients with Parkinson disease: a randomized controlled trial. *J Wound Ostomy Continence Nurs.* Jan-Feb 2015;42(1):94-99. PMID 25549314

22. Gaspard L, Tombal B, Opsomer RJ, et al. [Physiotherapy and neurogenic lower urinary tract dysfunction in multiple sclerosis patients: a randomized controlled trial]. *Prog Urol.* Sep 2014;24(11):697-707. PMID 25214451
23. Eftekhar T, Teimoory N, Miri E, et al. Posterior tibial nerve stimulation for treating neurologic bladder in women: a randomized clinical trial. *Acta Med Iran.* Nov 2014;52(11):816-821. PMID 25415813
24. Edenfield AL, Amundsen CL, Wu JM, et al. Posterior tibial nerve stimulation for the treatment of fecal incontinence: a systematic evidence review. *Obstet Gynecol Surv.* May 2015;70(5):329-341. PMID 25974730
25. Horrocks EJ, Thin N, Thaha MA, et al. Systematic review of tibial nerve stimulation to treat faecal incontinence. *Br J Surg.* Apr 2014;101(5):457-468. PMID 24446127
26. George AT, Kalmar K, Sala S, et al. Randomized controlled trial of percutaneous versus transcutaneous posterior tibial nerve stimulation in faecal incontinence. *Br J Surg.* Feb 2013;100(3):330-338. PMID 23300071
27. Knowles CH, Horrocks EJ, Bremner SA, et al. Percutaneous tibial nerve stimulation versus sham electrical stimulation for the treatment of faecal incontinence in adults (CONFIDeNT): a double-blind, multicentre, pragmatic, parallel-group, randomised controlled trial. *Lancet.* Oct 24 2015;386(10004):1640-1648. PMID 26293315
28. Thin NN, Taylor SJ, Bremner SA, et al. Randomized clinical trial of sacral versus percutaneous tibial nerve stimulation in patients with faecal incontinence. *Br J Surg.* Mar 2015;102(4):349-358. PMID 25644291
29. Gormley EA, Lightner DJ, Faraday M, et al. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU guideline amendment. *J Urol.* May 2015;193(5):1572-1580. PMID 25623739
30. ACOG Practice Bulletin No. 155: Urinary Incontinence in Women. *Obstet Gynecol.* Nov 2015;126(5):e66-81. PMID 26488524

POLICY HISTORY

Date	Action	Description
December 2012	New Policy	
September 2013	Update Policy	Policy updated with literature review. References 5, 6, 8-10, 12-15, 17 and 20 added; other references renumbered or removed. Policy statement unchanged.
September 2014	Update Policy	Policy updated with literature review; reference 1 added, 5 updated; policy statement unchanged.
September 2015	Update Policy	Policy updated with literature review; Title changed to “Percutaneous Tibial Nerve Stimulation.” “Posterior” changed to “percutaneous” in existing policy statement. Policy statement edited to not medically necessary for all indications with bullet points for urinary and fecal incontinence. Reference 17-19 added.
June 2016	Update Policy	Policy updated with literature review through November 30, 2015; references 15, 17, 19-25, 27-28, and 30-31 added. Policy statements unchanged.
June 2018	Update Policy	Policy updated with literature review through September 15, 2017; reference 18 added; reference 31 updated. Revised policy statements for use of PTNS in OAB syndrome that has failed behavioral and pharmacologic therapy. In these patients, PTNS is considered medically necessary as an initial course of therapy and maintenance therapy for individuals who respond to initial course. Percutaneous tibial nerve stimulation changed from not medically necessary to investigational (due to FDA 510k approval status) for all other indications, including but not limited to the following: Neurogenic bladder dysfunction; Fecal incontinence.