MEDICAL POLICY

POLICY TITLE	PERCUTANEOUS AND IMPLANTABLE TIBIAL NERVE STIMULATION
POLICY NUMBER	MP 1.134

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**4/1/2024**

POLICY
RATIONALE
DISCLAIMER
POLICY HISTORY
PRODUCT VARIATIONS
DEFINITIONS
CODING INFORMATION
DESCRIPTION/BACKGROUND
BENEFIT VARIATIONS
REFERENCES

I. POLICY

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 (see policy guidelines).

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 **investigational** for all other indications including, but not limited to, the following:

- Neurogenic bladder dysfunction; **or**
- Fecal incontinence

There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure for these indications.

Implantable tibial nerve stimulation is considered **investigationa**l, as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

POLICY GUIDELINES

Behavioral therapies may be combined with pharmacologic therapies. They do not have to occur in a sequential manner.

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

Cross-references:

MP 1.033 Sacral Nerve Neuromodulation/Stimulation and Pelvic Floor Stimulation Devices
MP 6.050 Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)
MP 2.064 Biofeedback and Neurofeedback Therapy
MP 1.109 Periureteral Bulking Agents as Treatment of Vesicoureteral Reflux
MP 2.096 Electromyography (EMG) (Needle and Non-Needle) of the Anal or Urethral Sphincter

II. PRODUCT VARIATIONS TOP

This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND TOP

Voiding Dysfunction

Common causes of non-neurogenic voiding dysfunction are pelvic floor neuromuscular changes (e.g., from pregnancy, childbirth, surgery), inflammation, medication (e.g., diuretics, anticholinergics), obesity, and psychogenic factors. Overactive bladder is a non-neurogenic voiding dysfunction characterized by urinary frequency, urgency, urge incontinence, and nonobstructive retention.

Neurogenic bladder dysfunction is caused by neurologic damage in patients with multiple sclerosis, spinal cord injury, detrusor hyperreflexia, or diabetes with peripheral nerve involvement. The symptoms include overflow incontinence, frequency, urgency, urge incontinence, and retention.

Treatment

Approaches to the treatment of incontinence differentiate between urge incontinence and stress incontinence. Conservative behavioral management such as lifestyle modification (e.g., dietary changes, weight reduction, fluid management, smoking cessation) along with pelvic floor exercises and bladder training are part of the initial treatment of overactive bladder symptoms and both types of incontinence. Pharmacotherapy is another option, and different medications target different symptoms. Some individuals experience mixed incontinence.

If behavioral therapies and pharmacotherapy are unsuccessful, percutaneous tibial nerve stimulation (PTNS), sacral nerve stimulation, or botulinum toxin may be recommended.

POLICY TITLE	PERCUTANEOUS AND IMPLANTABLE TIBIAL NERVE STIMULATION
POLICY NUMBER	MP 1.134

Percutaneous Tibial Nerve Stimulation
The current indication cleared by the U.S. Food and Drug Administration (FDA) for PTNS is overactive bladder and associated symptoms of urinary frequency, urinary urgency, and urge incontinence.

Altering the function of the posterior tibial nerve with PTNS is believed to improve voiding function and control. The mechanism of action is believed to be retrograde stimulation of the lumbosacral nerves (L4-S3) via the posterior tibial nerve located near the ankle.
The lumbosacral nerves control the bladder detrusor and perineal floor.

Administration of PTNS consists of inserting a needle above the medial malleolus into the posterior tibial nerve followed by the application of low-voltage (10 mA, 1-10 Hz frequency) electrical stimulation that produces sensory and motor responses as evidenced by a tickling sensation and plantarflexion or fanning of all toes. Noninvasive PTNS has also been delivered with transcutaneous or surface electrodes. The recommended course of treatment is an initial series of 12 weekly office-based treatments followed by an individualized maintenance treatment schedule.

PTNS is less invasive than traditional sacral nerve neuromodulation (see evidence review MP 1.033), which has been successfully used to treat 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.

PTNS has also been proposed as a treatment for non-neurogenic and neurogenic bladder syndromes and fecal incontinence.

Implantable Tibial Nerve Stimulation

Protect PNS Neurostimulator is a wirelessly powered, minimally invasive, microtechnology neurostimulator intended to treat overactive bladder (OAB). Protect PNS is currently being studied for the treatment of OAB and is under regulatory review for market approval by the FDA.

eCoin® is a subcutaneous tibial nerve stimulation (STNS) device. The current indication approved by the FDA for STNS is urgency urinary incontinence in individuals who are intolerant or who have had an inadequate response to more conservative treatments or who have undergone a successful trial of PTNS. STNS is administered through a coin-sized leadless battery-powered implant. STNS offers a less invasive alternative to traditional sacral nerve neuromodulation and offers a convenient delivery system for automated treatments without the need for chronic outpatient PTNS treatment sessions.

Regulatory Status
In 2005, the Urgent® PC Neuromodulation System was the initial PTNS device cleared for marketing by FDA through the 510(k) process 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 devices are not FDA-cleared for other indications, such as the treatment of fecal incontinence.

Wireless technology is evolving for the treatment of overactive bladder. In March 2022, the eCoin® Peripheral Neurostimulator System (Valencia Technologies Corporation) became the first subcutaneous tibial nerve stimulation implant approved by the FDA through the premarket authorization (PMA) process for individuals with urgency urinary incontinence (P200036; FDA Product Code: QPT).

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	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	Treatment of patients with overactive bladder and associated symptoms of urinary urgency, urinary frequency, and urge incontinence
ZIDA Wearable Neuromodulation System	Exodus Innovations	Mar 2021	K192731	Treatment of patients with an overactive bladder and associated symptoms of urinary urgency, urinary frequency, and urge incontinence

IV. RATIONALE

TOP

SUMMARY OF EVIDENCE

For individuals who have non-neurogenic urinary dysfunction including overactive bladder and 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 included these and other published trials have found short-term reductions in voiding dysfunction with PTNS. The largest, highest quality

study was the double-blinded, sham-controlled SUmiT trial, which 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 therapy 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 overactive bladder 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. Typical regimens schedule maintenance treatments every 4-6 weeks. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have non-neurogenic urinary dysfunction including overactive bladder and who have failed behavioral and pharmacologic therapy or who have responded to an initial course of PTNS and then receive subcutaneous tibial nerve stimulation (STNS), the evidence includes single-arm studies. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The pivotal open-label, single-arm study leading to FDA-approval of the subcutaneously-implanted, wireless eCoin tibial nerve stimulation system demonstrated a 68% response rate at 48 weeks of follow-up which surpassed a performance goal of 40%. However, the certainty of the evidence is limited by the lack of comparator group and a lower response rate observed during the COVID-19 pandemic. Additionally, the FDA noted that the performance goal was identified after patients had already been implanted. An ongoing post-approval study may elucidate the certainty of benefit, including safety of reimplantation given battery lifespan concerns. The evidence is insufficient to determine that the technology results in an 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 study populations and

comparator interventions. Study findings have not reported that tibial nerve stimulation significantly reduced incontinence symptoms and improved 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. A meta-analysis of a single RCT and several observational studies reported that patients receiving sacral nerve simulation experienced significant benefits compared with patients receiving PTNS. A post hoc analysis of the larger trial suggested a subset of patients with fecal incontinence (those without concomitant obstructive defecation) may benefit from PTNS. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. DEFINITIONS

TOP

URGE INCONTINENCE is defined as leakage of urine when there is a strong urge to void.

URGENCY-FREQUENCY is an uncontrollable urge to urinate, resulting in very frequent, small volumes.

URINARY RETENTION is the inability to completely empty the bladder of urine

VI. BENEFIT VARIATIONS

TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

TOP

Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's

plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

TOP

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

The following implantable neurostimulation devices are considered investigational; therefore, not covered:

Procedure Codes								
0587T*	0588T*	0589T*	0590T*	0816T	0817T	0818T	0819T	

*These codes may be used for the Protect PNS device which has not been FDA approved

Covered when medically necessary, for treatment of non-neurogenic urinary dysfunction via percutaneous tibial nerve stimulation devices:

Procedure Codes								
64566	E0736							

ICD-10-CM Diagnosis Code	Description
N32.81	Overactive bladder
N39.41	Urge incontinence
N39.42	Incontinence without sensory awareness
N39.43	Post-void dribbling
N39.44	Nocturnal enuresis
N39.45	Continuous leakage
N39.46	Mixed incontinence
N39.490	Overflow incontinence
N39.491	Coital incontinence
N39.492	Postural (urinary) incontinence
N39.498	Other specified urinary incontinence
R32	Unspecified urinary incontinence
R33.0	Drug induced retention of urine

ICD-10-CM Diagnosis Code	Description
R33.8	Other retention of urine
R33.9	Retention of urine, unspecified
R35.0	Frequency of micturition
R35.81	Nocturnal polyuria
R35.89	Other polyuria
R39.14	Feeling of incomplete bladder emptying
R39.15	Urgency of urination

IX. REFERENCES

TOP

1. *Wang M, Jian Z, Ma Y, et al. Percutaneous tibial nerve stimulation for overactive bladder syndrome: a systematic review and meta-analysis. Int Urogynecol J. Dec 2020; 31(12): 2457-2471. PMID 32681345*
2. *Xiong SC, Peng L, Hu X, et al. Effectiveness and safety of tibial nerve stimulation versus anticholinergic drugs for the treatment of overactive bladder syndrome: a meta-analysis. Ann Palliat Med. Jun 09 2021. PMID 34118839*
3. *Coolen RL, Groen J, Scheepe JR, et al. Transcutaneous Electrical Nerve Stimulation and Percutaneous Tibial Nerve Stimulation to Treat Idiopathic Nonobstructive Urinary Retention: A Systematic Review. Eur Urol Focus. Oct22 2020. PMID 33268327*
4. *Ho FCS, He C, Yao HH, et al. Efficacy of sacral neuromodulation and percutaneous tibial nerve stimulation in the treatment of chronic nonobstructive urinary retention: A systematic review. Neurourol Urodyn. Jun 2021; 40(5):1078-1088. PMID 33973670*
5. *Tutolo M, Ammirati E, Heesakkers J, et al. Efficacy and Safety of Sacral and Percutaneous Tibial Neuromodulation in Non-neurogenic Lower Urinary Tract Dysfunction and Chronic Pelvic Pain: A Systematic Review of the Literature. Eur Urol. Mar 2018; 73(3): 406-418. PMID 29336927*
6. *Tutolo M, Ammirati E, Van der Aa F. What Is New in Neuromodulation for Overactive Bladder?. Eur Urol Focus. Jan 2018; 4(1): 49-53. PMID 29773501*
7. *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*
8. *Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Percutaneous tibial nervestimulation for the treatment of voiding dysfunction. TEC Assessments. 2013;Volume 28:Tab 10.*
9. *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): 1206-16. PMID 22581511*

10. *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): 1591-7. PMID 22411208*
11. *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): 206-14. PMID 22907807*
12. *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*
13. *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.*
14. *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): 2001-6. PMID 20850833*
15. *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): 1438-43. PMID 20171677*
16. *Peters K, Carrico D, Burks F. Validation of a sham for percutaneous tibial nerve stimulation (PTNS). Neurourol Urodyn. 2009; 28(1): 58-61. PMID 18671297*
17. *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. Jun 2013; 189(6): 2194-201. PMID 23219541*
18. *Vecchioli-Scaldazza C, Morosetti C. Effectiveness and durability of solifenacin versus percutaneous tibial nerve stimulation versus their combination for the treatment of women with overactive bladder syndrome: a randomized controlled study with a follow-up of ten months. Int Braz J Urol. Jan-Feb 2018; 44(1): 102-108. PMID 29064651*
19. *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.e1-10. PMID 25979217*
20. *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. 2013; 75(1): 46-52.PMID 23171636*
21. *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: 51-6. PMID 26073262*
22. *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. 2013; 75(4): 230-4. PMID 23548260*
23. *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): 1065-70. PMID 20458465*

24. *Peters KM, Macdiarmid SA, Wooldridge LS, et al. Randomized trial of percutaneous tibial nerve stimulation versusextended-release tolterodine: results from the overactive bladder innovative therapy trial. J Urol. Sep 2009; 182(3):1055-61. PMID 19616802*
25. *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): 234-40. PMID 19913821*
26. *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): 859-67. PMID 26194043*
27. *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): 509-14. PMID 25168524*
28. *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): 94-9. PMID 25549314*
29. *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*
30. *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. 2014; 52(11): 816-21. PMID 25415813*
31. *Zonic-Imamovic M, Imamovic S, Cickusic A, et al. Effects of Treating an Overactive Urinary Bladder in Patients with Multiple Sclerosis. Acta Med Acad. Dec 2019; 48(3): 271-277. PMID 32124625*
32. *Welk B, McKibbon M. A randomized, controlled trial of transcutaneous tibial nerve stimulation to treat overactive bladder and neurogenic bladder patients. Can Urol Assoc J. Jul 2020; 14(7): E297-E303. PMID 32017693*
33. *Sarveazad A, Babahajian A, Amini N, et al. Posterior Tibial Nerve Stimulation in Fecal Incontinence: A SystematicReview and Meta-Analysis. Basic Clin Neurosci. Sep-Oct 2019; 10(5): 419-431. PMID 32284831*
34. *Tan K, Wells CI, Dinning P, et al. Placebo Response Rates in Electrical Nerve Stimulation Trials for Fecal Incontinence and Constipation: A Systematic Review and Meta-Analysis. Neuromodulation. Dec 2020; 23(8): 1108-1116. PMID 31889364*
35. *Simillis C, Lal N, Qiu S, et al. Sacral nerve stimulation versus percutaneous tibial nerve stimulation for faecal incontinence: a systematic review and meta-analysis. Int J Colorectal Dis. May 2018; 33(5): 645-648. PMID* 9470730
36. *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): 329-41. PMID 25974730*
37. *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): 457-68. PMID 24446127*
38. *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): 330-8. PMID 23300071*

39. *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): 1640-8. PMID 26293315*
40. *Horrocks EJ, Chadi SA, Stevens NJ, et al. Factors Associated With Efficacy of Percutaneous Tibial Nerve Stimulation for Fecal Incontinence, Based on Post-Hoc Analysis of Data From a Randomized Trial. Clin Gastroenterol Hepatol. Dec 2017; 15(12): 1915-1921.e2. PMID 28647458*
41. *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): 349-58. PMID 25644291*
42. *Leo CA, Thomas GP, Hodgkinson JD, et al. Randomized Pilot Study: Anal Inserts Versus Percutaneous Tibial Nerve Stimulation in Patients With Fecal Incontinence. Dis Colon Rectum. Apr 01 2021; 64(4): 466-474. PMID 33399411*
43. *Sanagapalli S, Neilan L, Lo JYT, et al. Efficacy of Percutaneous Posterior Tibial Nerve Stimulation for the Management of Fecal Incontinence in Multiple Sclerosis: A Pilot Study. Neuromodulation. Oct 2018; 21(7): 682-687. PMID 29575432*
44. *Lightner DJ, Gomelsky A, Souter L, et al. Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults: AUA/SUFU Guideline Amendment 2019. J Urol. Sep 2019; 202(3): 558-563. PMID 31039103*
45. *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*
46. *ACOG Practice Bulletin No. 155: Urinary Incontinence in Women. Obstet Gynecol. Nov 2015; 126(5): e66-e81.PMID 26488524*
47. *Bharucha AE, Rao SSC, Shin AS. Surgical Interventions and the Use of Device-Aided Therapy for the Treatment of Fecal Incontinence and Defecatory Disorders. Clin Gastroenterol Hepatol. Dec 2017; 15(12): 1844-1854. PMID*
48. *Lukacz, E. Female urinary incontinence: Treatment. In: UpToDate Online Journal [serial online]. Waltham, MA: UpToDate; updated July 13, 2022*
49. *van Breda HMK, Martens FMJ, Tromp J, Heesakkers JPFA. A New Implanted Posterior Tibial Nerve Stimulator for the Treatment of Overactive Bladder Syndrome: 3-Month Results of a Novel Therapy at a Single Center. J Urol. 2017 Jul;198(1):205-210. PMID: 28189576.*
50. *MacDiarmid S, Staskin DR, Lucente V, Kaaki B, English S, Gilling P, Meffan P, Clark M, Sand PK, Sen SK, Rovner E. Feasibility of a Fully Implanted, Nickel Sized and Shaped Tibial Nerve Stimulator for the Treatment of Overactive Bladder Syndrome with Urgency Urinary Incontinence. J Urol. 2019 May;201(5):967-972. PMID: 31009968.*
51. *Kaaki B, English S, Gilling P, Meffan P, Lucente V, MacDiarmid S, et al. Six-Month Outcomes of Reimplantation of a Coin-Sized Tibial Nerve Stimulator for the Treatment of Overactive Bladder Syndrome With Urgency Urinary Incontinence. Female Pelvic Med Reconstr Surg. 2022 May 1;28(5):287-292 PMID: 35536667*
52. *Rogers A, Bragg S, Ferrante K, Thenuwara C, Peterson DKL. Pivotal Study of Leadless Tibial Nerve Stimulation with eCoin® for Urgency Urinary Incontinence: An Open-Label, Single Arm Trial. J Urol. 2021Aug;206(2):399-408 PMID: 33797291*

53. United States Food and Drug Administration (FDA). PMA database. P200036. ECoin® Peripheral Neurostimulator. 2022 July.
54. Ginsberg DA, Boone TB, Cameron AP et al: The AUA/SUFU Guideline on Adult Neurogenic Lower Urinary Tract Dysfunction: Treatment and Follow-up. J Urol 2021; 206: 1106.
55. Tudor KI, Seth JH, Liechti MD, et al. Outcomes following percutaneous tibial nerve stimulation (PTNS) treatment for neurogenic and idiopathic overactive bladder. Clin Auton Res. 2020;30(1):61-67. doi:10.1007/s10286-018-0553-8
56. Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.106, Percutaneous Tibial Nerve Stimulation. September 2023

X. POLICY HISTORY

TOP

MP 1.034	**4/17/20 Consensus review**. Policy statement unchanged. Background and references updated. Coding section corrected to separate medically necessary from investigational codes.
	9/24/21 Consensus review. Policy statement unchanged. FEP language updated. References updated.
	11/22/2022 Minor review. INV statement for implantable tibial nerve stimulation. References, background, and rationale updated.
	10/9/2023 Consensus review. Updated policy guidelines, background, rationale, coding table, and references.
	12/12/23 Administrative review. Added 0816T-0819T
	3/15/2024 Administrative review. Added E0736. Effective 4/1/2024

Top