MEDICAL POLICY

POLICY TITLE	PERCUTANEOUS TIBIAL NERVE STIMULATION
POLICY NUMBER	MP-1.134

Original Issue Date (Created):	**9/1/2012**
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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.

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; **or**
- Fecal incontinence.

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

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.

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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.

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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.

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 Urgent® PC Neuromodulation System and NURO™ Neuromodulation System and ZIDA Wearable Neuromodulation System are not FDA-cleared for other indications, such as the treatment of fecal incontinence.
Wireless technology is evolving for the treatment of overactive bladder; it is approved in Europe. BlueWind (BlueWind Medical) is a wireless, battery-less, miniature implantable neurostimulator 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	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

FDA: Food and Drug Administration.

IV. RATIONALE

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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 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.

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V. DEFINITIONS

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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

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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

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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

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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 integrated single device neurostimulation devices are considered investigational; therefore, not covered:

CPT Codes®								
0587T	0588T	0589T	0590T					

Covered when medically necessary, for treatment non-neurogenic urinary dysfunction:

CPT Codes®								
64566								

ICD-10-CM Diagnosis Codes	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
R33.8	Other retention of urine
R33.9	Retention of urine, unspecified
R35.0	Frequency of micturition
R39.15	Urgency of urination

IX. REFERENCES

TOP

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X. POLICY HISTORY

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MP 1.034	**CAC 4/24/2012 New Policy.** Adopted BCBSA. Posterior tibial nerve stimulation for voiding dysfunction is considered investigational.
	10/8/12 Medicare variation added to indicate procedure code 64566 Posterior tibial neurostimulation, percutaneous stimulation, including programming, is considered Medically Necessary for Sr Blue HMO and Sr Blue PPO.
	6/4/13 CAC **Consensus review**. Administrative code review complete**.**
	6/19/13 Admin Update. Changed Medicare variation to reference LCD L33083 effective 8/1/13 rather than L31686
	CAC 3/25/14 Consensus review. No change to policy statements. References updated. Rationale section added. Coding reviewed.
	CAC 3/24/15 Minor revision. Title changed to Percutaneous Tibial Nerve Stimulation. "Posterior" changed to "percutaneous" in existing policy statement. Policy statement edited to investigational for all indications with bullet points for urinary and fecal incontinence. Reference and rationale updated. Coding reviewed.

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	11/2/15 Admin Update. LCD number changed from L33083 to L35011 due to Novitas update to ICD-10
	CAC 3/29/16 Consensus review. No changes to the policy statements. References and rationale updated. Coding reviewed.
	1/1/17 Admin Update. Variation reformatting.
	CAC 5/23/17 Consensus review. No change to policy statements. References reviewed. Coding Reviewed.
	1/1/18 Admin Update. Medicare variations removed from Commercial Policies.
	2/26/18 Consensus review. No change to the policy statement. References reviewed.
	4/26/18 Minor review. 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. Updated references and background. Condensed rationale. Coding Updated.
	4/2/19 Consensus review. No change to policy statements. Summary of evidence, background and references updated.
	1/1/20 Admin Update. Added 0587T, 0589T, 0590T, and 0590T.
	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.

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