02-64000-01

Original Effective Date: 05/15/08

Reviewed: 10/24/24

Revised: 11/15/24

Subject: Percutaneous and Subcutaneous Tibial Nerve Stimulation

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Percutaneous tibial nerve stimulation (PTNS; also known as posterior tibial nerve stimulation) is an electrical neuromodulation technique used primarily for treating voiding dysfunction. Altering the function of the posterior tibial nerve with PTNS is believed to improve voiding function and control. 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. The recommended course of treatment is an initial series of 12 weekly office-based treatments followed by an individualized maintenance treatment schedule. PTNS has also been proposed as a treatment for non-neurogenic and neurogenic bladder syndromes and fecal incontinence.

Subcutaneous tibial nerve stimulation (STNS) via an implantable peripheral neurostimulator is an alternate technique for treating urgency urinary incontinence associated with overactive bladder syndrome. The current indication for subcutaneous tibial nerve stimulation (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 delivered by an implantable peripheral neurostimulator system (eg. eCoin®).

Summary and Analysis of Evidence: Individuals treated with an initial course of PTNS who have non-neurogenic urinary dysfunction including overactive bladder and have failed behavioral and pharmacologic therapy, the evidence includes randomized sham-controlled trials, randomized controlled trials (RCTs) with an active comparator, and systematic reviews. The Sham Effectiveness in Treatment of Overactive Bladder Symptoms (SUmiT) and the Overactive Bladder Innovative Therapy (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-blind, sham-controlled SUmiT trial, which reported a statistically significant benefit of PTNS versus sham at 12 weeks. In an additional, small sham-controlled trial, a 50% reduction in urge incontinent episodes was attained in 71% of the PTNS group compared with 0% in thesham group. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. For individuals who have overactive bladder syndrome that have failed behavioral and pharmacologic therapy who respond to an initial course of PTNS and who receive maintenance PTNS, the evidence includes observational studies and systematic reviews. The SUmiT and 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. Percutaneous tibial nerve stimulation 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 an improvement in the net health outcome. 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 STNS, the evidence includes single-arm studies. 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. PTNS for the treatment of neurogenic bladder dysfunction, the evidence includes several RCTs and systematic review of RCTs and observational data. Only a few RCTs evaluating tibial nerve stimulation for treating neurogenic bladder have been published to date, and all but 1 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 that the technology results in an improvement in the net health outcome. PTNS for the treatment of fecal incontinence, the evidence includes several RCTs and systematic reviews.The available RCTs have not found a clear benefit of PTNS. None of the sham-controlled trials found that active stimulation was superior to sham for achieving a 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. An additional sham-controlled randomized trial did not identify a benefit of PTNS over sham stimulation. A meta-analysis of a single RCT and several observational studies reported that patients receiving sacral nerve stimulation experienced significant benefits compared with patients receiving PTNS. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

POSITION STATEMENT:

Percutaneous tibial nerve stimulation (PTNS) for an initial 12-week course **meets the definition of medical necessity** for members 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 PTNS **meets the definition of medical necessity** for members following a 12-week initial course of PTNS that resulted in improved urinary dysfunction meeting treatment goals.

If the member fails to improve after an initial 12-week course, continued treatment **does not meet the definition of medical necessity**.

PTNS is considered **experimental or investigational** for all other indications, including but not limited to the following:

- Neurogenic bladder dysfunction
- Fecal incontinence.

The evidence is insufficient to determine the effects of the technology on health outcomes.

Subcutaneous tibial nerve stimulation delivered by an implantable peripheral neurostimulator system (e.g., eCoin) is considered **experimental or investigational** for all indications, including members with non-neurogenic urinary dysfunction and overactive bladder. The evidence is insufficient to determine the effects of the technology on health outcomes.

BILLING/CODING INFORMATION:

CPT Coding:

There is no specific CPT or HCPCS code to report subcutaneous tibial nerve stimulation delivered by an implantable peripheral neurostimulator system. It may be billed with code 64590 or 64999.

64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming
0587T	Percutaneous implantation or replacement of integrated single device neurostimulation system for bladder dysfunction including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve (**Investigational**)
0588T	Revision or removal of percutaneously placed integrated single device neurostimulation system for bladder dysfunction including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve (**Investigational**)

0589T	Electronic analysis with simple programming of implanted integrated neurostimulation system for bladder dysfunction (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, posterior tibial nerve, 1-3 parameters (**Investigational**)
0590T	Electronic analysis with complex programming of implanted integrated neurostimulation system for bladder dysfunction (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patients-electable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, posterior tibial nerve, 4 or more parameters (**Investigational**)
0816T	Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (eg, array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subcutaneous (**Investigational**)
0818T	Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subcutaneous (**Investigational**)

ICD-10 Diagnosis Codes That Support Medical Necessity:

N32.81	Overactive bladder
N39.41 – N39.498	Other specified urinary incontinence
R33.0 – R33.9	Retention of urine
R35.0	Frequency of micturition
R39.15	Urgency of urination

REIMBURSEMENT INFORMATION:

A total of twelve (12) treatments (one per week) will initially be approved if criteria are met. If a 12-week course results in improved urinary dysfunction meeting treatment goals an additional nine months of maintenance therapy (one per month) may be approved if there is documented continued improvement.

Code 64566 is limited to one (1) unit of service per member date of service.

Reimbursement for an initial 12-week course of PTNS and maintenance therapy using monthly PTNS will be covered only when the criteria above are met and there is documented evidence that the therapy continues to result in improved urinary dysfunction meeting treatment goals. The following information may be required documentation to support medical necessity: physician history and physical, attending physician visit notes, attending physician treatment plan, attending physician progress notes including documentation of the 12-week initial course of PTNS that resulted in improved urinary dysfunction meeting treatment goals.

LOINC Codes:

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Attending physician visit notes	18733-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Attending physician progress note	18741-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Treatment plan	18776-5	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage Products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) was found at the time of the last guideline reviewed date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

None applicable.

RELATED GUIDELINES:

Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence, 09-A9000-03

Pelvic Floor Stimulation as a Treatment of Incontinence, 01-97000-06

Percutaneous Electrical Nerve Stimulation (PENS), 02-61000-03

Sacral Nerve Neuromodulation/Stimulation, 02-61000-23

Transanal Radiofrequency Therapy as a Treatment of Fecal Incontinence, 01-91000-07

Transvaginal Radiofrequency Bladder Neck Suspension and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence, 02-50000-16

OTHER:

None applicable.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 10/24/24.

GUIDELINE UPDATE INFORMATION:

05/15/08	New Medical Coverage Guideline.
05/15/09	Annual review: position statement maintained and references updated.
04/15/10	Annual review: position statement maintained; Medicare Advantage program exception and references updated.
01/01/11	Annual HCPCS coding update. Added 64566.

03/15/11	Annual review; position statement maintained and references updated.
06/15/12	Annual review; position statement maintained, Program Exceptions section and references updated.
07/15/13	Annual review; position statement maintained, description section and references updated.
05/15/14	Annual review; position statement maintained and references updated.
03/15/15	Annual review; description section, position statement, title, and references updated.
11/01/15	Revision: ICD-9 Codes deleted.
06/15/18	Revision; position statements, description, coding, and references updated.
10/15/19	Review; position statements maintained; description section and references updated.
01/01/20	Annual CPT/HCPCS coding update. Added codes 0587T-0590T.
10/15/20	Review; position statements maintained and references updated.
11/15/21	Review: Position statements maintained; references updated.
08/21/23	Update to Program Exceptions section.
11/15/23	Review: Subcutaneous tibial nerve stimulation statement added; title and references updated.
01/01/24	Annual CPT/HCPCS coding update. Codes 0816T, 0818T added; codes 0587T-0590T revised.
11/15/24	Review: Position statements maintained; description and references updated.