02-64000-01

Original Effective Date: 05/15/08

Reviewed: 05/24/18

Revised: 06/15/18

Subject: Percutaneous 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:

Common causes of voiding dysfunction are pelvic floor neuromuscular changes (eg, from pregnancy, childbirth, surgery), inflammation, medication (eg, diuretics, anticholinergics), obesity, psychogenic factors, and disease (eg, multiple sclerosis, spinal cord injury, detrusor hyperreflexia, diabetes with peripheral nerve involvement).

Altering the function of the posterior tibial nerve with percutaneous tibial nerve stimulation (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. Overactive bladder is voiding dysfunction that is characterized by urinary frequency, urgency, urge incontinence, and nonobstructive retention. Approaches to the treatment of incontinence differentiate between urge incontinence and stress incontinence. Conservative behavioral management such as lifestyle modification (eg, 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 an additional option, and different medications target different symptoms. Some individuals experience mixed incontinence.

Several percutaneous tibial nerve stimulators have been cleared for marketing by the U.S. Food and Drug Administration (FDA). The current indication cleared by the FDA for PTNS is overactive bladder and associated symptoms of urinary frequency, urinary urgency, and urge incontinence.

The procedure for PTNS consists of the insertion of 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 monthly maintenance therapy if the patient responded to the initial course of PTNS.

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.

BILLING/CODING INFORMATION:

CPT Coding:

64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming

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: The following Local Coverage Determination (LCD) was reviewed on the last guideline reviewed date: Posterior Tibial Nerve Stimulation (PTNS) (L33406) located at fcso.com.

DEFINITIONS:

Neurogenic Bladder: bladder dysfunction due to neurologic damage originating from internal or external trauma, disease, or injury

RELATED GUIDELINES:

Pelvic Floor Stimulation as a Treatment of Incontinence, 01-97000-06
Sacral Nerve Neuromodulation/Stimulation, 02-61000-23
Transvaginal Radiofrequency Bladder Neck Suspension 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 & Coverage Committee on 05/24/18.

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.