Medical Policy:

Posterior Tibial Nerve Stimulation for Voiding Dysfunction

POLICY NUMBER	LAST REVIEW
MG.MM.ME.67dC	January 12, 2024

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Percutaneous Tibial Nerve Stimulation (PTNS)	A technique of electrical neuromodulation for the treatment of voiding dysfunction in patients who have failed behavioral and /or pharmacologic therapies. This is the least invasive form of neuromodulation used to treat overactive bladder (OAB) and the associated symptoms of urinary urgency, urinary frequency and urge incontinence. Common causes of voiding dysfunction are pelvic floor dysfunction (e.g., from pregnancy, childbirth, surgery), inflammation, medication (e.g., diuretics and anticholinergics), obesity, psychogenic factors, and disease (e.g., multiple sclerosis, spinal cord injury, detrusor hyper-reflexia). PTNS treatment consists of a series of short-term insertions of a percutaneous needle electrode for approximately 30 minutes, with intermittent neuromodulation while the needle electrode remains in place. The neurostimulator includes a lead set with surface electrodes and a needle electrode, which produces an adjustable electrical pulse that travels to the sacral nerve plexus via the tibial nerve. The sacral nerve plexus then regulates the bladder and the pelvic floor functionality.
Increased Daytime Frequency	The complaint by the individual who considers that he/she voids too often during the day.

Nocturia	The complaint that the individual has to wake at night one or more times to urinate.
Urgency	The complaint of a sudden compelling desire to pass urine, which is difficult to defer.
Urinary Incontinence	The complaint of any involuntary leakage of urine.

Guideline

Treatment with PTNS for OAB in the office setting is considered medically necessary when all the following criteria are documented as met:

1. Evaluation by an appropriate specialist (e.g., urologist or urogynecologist) who has determined that the member is a candidate for PTNS
2. Failure of behavioral therapies/medical management (which may be concurrent) for a period of ≥ 3 months duration
3. Failure/intolerance/contraindication to pharmacotherapy with ≥ 2 overactive bladder medications such as an anticholinergic and/or β3 agonist administered for 4–8 weeks

Limitations/Exclusions

1. Initial course of PTNS treatment is defined as one 30-minute session per week for 12 consecutive weeks.
2. Continuation of PTNS is covered for members who complete and show response to the 12-week treatment regimen.

   Response is defined as ≥ 50% improvement in voiding symptoms (based on documentation such as patient voiding diaries). The treatment regimen for continued PTNS is tailored to each individual member; typically 1 treatment administered every 2–3 weeks (26 treatments per 12 month maximum).
3. Treatment with PTNS is not considered medically necessary for any of the following conditions due to insufficient evidence of therapeutic value (list not all-inclusive):
   a. Chronic pelvic pain
   b. Constipation
   c. Fecal incontinence
   d. Voiding dysfunction secondary to a neurological condition
4. Implantable tibial nerve stimulation (e.g., eCoin Peripheral Neurostimulator System) is not considered medically necessary due to insufficient evidence of therapeutic value.

Procedure Codes

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

ICD-10 Diagnoses

N32.81	Overactive bladder
N39.41	Urge incontinence

R35.0	Frequency of micturition
R39.15	Urgency of urination

References

Agency for Healthcare Research and Quality. Comparative effectiveness review number 36. Nonsurgical treatments for urinary incontinence in adult women: diagnosis and comparative effectiveness. 2012. https://www.ncbi.nlm.nih.gov/pubmed/22624162. Accessed January 23, 2024.

American Urological Association (AUA) and Society of Urodynamics FPMURS. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults/AUA/SUFU guideline 2012; Amended 2014, 2019. https://www.auanet.org/guidelines-and-quality/guidelines/overactive-bladder-(oab)-guideline. Accessed January 23, 2024..

National Government Services. Local Coverage Determination (LCD): Posterior Tibial Nerve Stimulation for Voiding Dysfunction. October 2019. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33396&ver=10&keywordtype=starts&keyword=Posterior%20Tibial%20Nerve%20Stimulation&bc=0. Accessed January 23, 2024.

Hayes Inc. Evolving Evidence Revies. eCoin Peripheral Neurostimulator System (Valencia Technologies Corp.) for Urgency Urinary Incontinence. Hayes, Inc.; September 8, 2022.

Specially matched clinical peer review.

Revision History

Company(ies)	DATE	REVISION
EmblemHealth ConnectiCare	Jan. 19, 2023	eCoin added as an investigational device example to implantable nerve stimulation
EmblemHealth ConnectiCare	Jan. 8, 2021	Removed in-office treatment sessions and voiding diary prerequisites.
EmblemHealth ConnectiCare	Jan. 10, 2020	Added implantable TNS to Limitations/Exclusions as investigational.
EmblemHealth ConnectiCare	Jul. 12, 2019	The indication of failure/intolerance/contraindication to pharmacotherapy with ≥ 2 anticholinergic medications and/or smooth muscle relaxants was clarified to include overactive bladder and β3 agonist medications.