Molina Clinical Policy
Implanted Tibial Nerve Stimulation for Urinary Incontinence: MEDICARE
Policy No. 473b

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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. 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 (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Overactive bladder (OAB) syndrome is a chronic condition that affects both men and women, with prevalence increasing with age. In the United States, the number of women affected by urinary incontinence is projected to increase from 18.3 million in 2010 to 28.4 million by 2050 (Wu et al. 2009). OAB is characterized by urinary urgency with or without incontinence, usually accompanied by increased daytime frequency and nocturia, and in the absence of urinary tract infection or other identifiable etiology. OAB may be caused by involuntary contractions of the detrusor muscle during the bladder filling phase, though the exact etiology can be multifactorial, including neurogenic and idiopathic factors (Scarneciu et al. 2021).

Urgency urinary incontinence (UUI) is defined as an involuntary loss of urine associated with urgency and is one of the major types of incontinence. While not all patients with OAB experience incontinence, most people with UUI are also diagnosed with OAB syndrome. UUI is often considered a more severe manifestation of OAB and is associated with greater impairment in quality of life, leading to functional and psychosocial burden. First-line therapy typically includes behavioral treatment, such as bladder training, urge control techniques, pelvic muscle training, caffeine reduction, fluid management, and dietary changes. Behavioral therapies may also be combined with pharmacological agents, such as antimuscarinic agents (e.g., oxybutynin) or oral β3-adrenoceptor agonists (e.g., mirabegron).

For patients who do not achieve adequate symptom improvement or who experience intolerable side effects from noninvasive and pharmacologic treatment, minimally invasive therapies may be considered, such as botulinum toxin injections or neuromodulation (e.g., sacral nerve stimulation [SNS], percutaneous tibial nerve stimulation [PTNS], or implantable tibial nerve stimulation). In PTNS, a needle electrode is temporarily inserted through the skin to stimulate the posterior tibial nerve near the ankle and is a session-based therapy. The sessions require patients to attend outpatient appointments, typically over 12 weeks followed by maintenance sessions (Cameron et al. 2024; Hayes 2024).

Implanted tibial nerve stimulation (ITNS), also called posterior tibial nerve stimulation, is a form of neuromodulation used to treat UUI. As the tibial nerve is a branch of the sciatic nerve, which originates from the same sacral nerve roots that control bladder and pelvic floor function, stimulation of the nerve may indirectly influence bladder control and help reduce symptoms of UUI. ITNS devices are implanted subcutaneously or subfascially near the posterior tibial nerve, typically in an outpatient office under local anesthesia. Once implanted, the device delivers automated electrical stimulation sessions at regular intervals and typically does not require repeated in-office visits, as with PTNS (Hayes 2024; Yamashiro et al. 2019).

Regulatory Status

ITNS devices are regulated by the FDA as Class II or III medical devices, depending on whether all system components are fully implantable (e.g., lead, battery, and pulse generator). Class II devices, such as the Revi System (BlueWind Medical), use an external power source and are cleared through the 510(k) pathway under product code QXM. Class III devices, such as the eCoin Peripheral Neurostimulator System (Valencia Technologies) are fully implantable systems, which include an internal battery and pulse generator, requiring premarket approval under product code QPT.

Other devices, such as the Intibia System (Nine Continents Medical/Coloplast) are currently under investigation.

COVERAGE POLICY

Implanted tibial nerve stimulation (ITNS) devices (e.g., eCoin Peripheral Neurostimulator System, Revi System) for the treatment of urgency urinary incontinence (UUI) or overactive bladder (OAB) are considered **experimental, investigational, and unproven** due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

SUMMARY OF MEDICAL EVIDENCE

Systematic Reviews and Meta-Analyses

Amundsen et al. (2025) performed a systematic review and meta-analysis to indirectly compare the safety and efficacy of implantable tibial nerve stimulation (ITNS) and sacral nerve stimulation (SNS) for treating overactive bladder (OAB). The review included 20 studies, including 3 randomized controlled trials, 10 prospective interventional studies, one prospective observational study, and 6 retrospective reviews, for a total of 1,766 patients (1,416 treated with SNS and 350 with ITNS). Follow up durations varied, averaging 13.0 months for ITNS and 39.2 months for SNS. Primary efficacy outcomes were the percentage of patients achieving a ≥ 50% reduction in urgency urinary incontinence (UUI) episodes and overall OAB symptoms, measured by voiding diaries. The weighted UUI responder rate was 71.8% for SNS and 71.3% for ITNS. Weighted averages for OAB were 73.9% for SNS and 79.4% for ITNS. Secondary outcomes included reductions in mean daily UUI episodes (3.5 for SNS and 3.0 for ITNS) and urinary frequency (5.5 for SNS and 2.0 for ITNS). Improvements in quality of life were generally measured with the OAB-q questionnaire, with a ≥ 10-point improvement seen in 48.4% of SNS patients and 83.2% of ITNS, and average score increases of 35.1 and 34.5 points respectively. Patient satisfaction was higher with ITNS (95.0%) compared to SNS (75.5%). Device and procedure related safety profiles were favorable for both neuromodulation modalities. Device-related adverse events occurred in 12.7% of SNS patients and 9.6% for ITNS. Rates of surgical revision and explants were higher for SNS (5.6-26.8%) than ITNS (0-1.7%), which may be attributed to differences in device design and procedure complexity. Both therapies showed low rates of pain, infection, and wound complications, and findings remained consistent across different study designs. All ITNS studies lacked a pre-implantation trial phase, unlike 14 of the 16 SNS studies. As ITNS devices use cyclic stimulation regimens and SNS devices use continuous stimulation, the impact of stimulation modes on long-term outcomes remains under investigation. Limitations of the review include absence of direct head-to-head comparisons, follow-up durations, and study designs. Eleven of the studies were rated as having moderate bias, mostly due to lack of randomization or blinding, single-center design, or retrospective methodology.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Sethi and Peters (2025) conducted a first-in-human, single-arm feasibility study to evaluate the preliminary safety and efficacy of the Intibia System, a novel ITNS device for treating OAB. The study enrolled 10 participants with refractory OAB who failed conservative treatments and at least two pharmacologic therapies. Following implantation of the ITNS device and a four week healing period, patients received two weeks of daily stimulation followed by 13 weeks of weekly stimulation. Primary outcomes assessed included urinary symptoms via a three-day bladder diary, patient-reported outcomes using the OAB-questionnaire short form (OAB-q SF) and a Global Response Assessment (GRA) scale. After 13 weeks of therapy, a reduction in the number of daily voids during waking hours (8.5 ± 2.5 to 6.3 ± 1.9; $p = 0.016$), incontinence episodes (2.5 ± 1.8 to 0.3 ± 0.5; $p < 0.001$), and daily voids associated with urgency (7.6 ± 3.1 to 3.0 ± 3.1; $p < 0.001$) were reported. Additionally, urgency severity was significantly alleviated, with a reduction in severe urgency episodes from 1.6 ± 1.9 to 0.5 ± 0.7 ($p = 0.035$). Eight out of ten patients were classified as responders, defined as having at least a 50% improvement in one or more OAB symptoms without worsening of others. One patient experienced worsening urgency symptoms, and one was a non-responder. The OAB-q SF severity score decreased

from 58.3 ± 24.5 to 18.3 ± 12.4 ($p < 0.001$). Nine adverse events were reported, including minor incision site issues and two urinary tract infections, all of which resolved with standard treatment. The authors concluded that the trial demonstrated preliminary safety and efficacy of the ITNS device in a small sample of patients with refractory OAB and showed substantial improvement in urinary symptoms and quality of life. (ClinicalTrials.gov NCT04115228).

Heesakkers et al. (2024) conducted a prospective, open-label, single-arm pivotal clinical trial to evaluate the safety and effectiveness of the Revi System by BlueWind Medical, an ITNS device for the treatment of UUI in adult women. The trial enrolled 151 eligible women with a mean age of 58.8 years who had a diagnosis of UUI and were appropriate candidates for third-line therapy after failing conservative and pharmacologic treatments. Patients were followed for 12 months post-treatment activation, with assessments conducted at 1, 3, 6, 9, and 12 months. The primary efficacy endpoint was the proportion of patients achieving at least a 50% reduction in average daily UUI episodes at 6 months. In the intent-to-treat analysis, 76.4% and 78.4% of participants were responders at 6 and 12 months respectively ($p < 0.0001$). Among those with complete 12-month data, 82% met the response threshold, 50% experienced no leaks on at least three consecutive diary days, and 93.5% reported symptom improvement. Secondary endpoints supported the primary findings. Statistically significant improvements were seen in OAB-specific quality of life, measured by OAB-q questionnaire, with 84% showing a ≥ 10-point improvement at 12 months. Reductions in large leakage episodes, voiding frequency, nocturia, and urgency severity, as measured by the Patient Perception of Intensity and Urgency Scale, were also significant. Mean UUI episodes declined from 4.8/day at baseline to 1.2/day at 12 months, a 74.3% reduction. Compliance with therapy was high, with over 90% of participants maintaining at least one treatment session per day throughout the study. Device-related adverse events occurred in 6 participants (4.0%) and were limited to stimulation-related pain, all of which resolved or were manageable. Procedure-related adverse events occurred in 16 participants (10.6%), including 10 wound-related events (6.6%) such as mild infections and dehiscence, all of which resolved without sequelae. While the study was limited to female participants, the device received FDA approval for both sexes. High rates of satisfaction (> 93%) and willingness to continue therapy at 12 months (94%) were also reported. The authors concluded that the Revi System offers a minimally invasive, safe, and effective long-term treatment for UUI (ClinicalTrials.gov NCT03596671).

Rogers et al. (2021) conducted a prospective, open-label, single-arm, pivotal clinical trial to evaluate the safety and efficacy of eCoin, a leadless ITNS device for the treatment of refractory UUI. The study enrolled 137 participants (132 intention-to-treat) across 15 Unites States medical centers. The population was predominantly female (98%) with a mean age of 63.9 years and an average baseline of 4.3 daily UUI episodes. All subjects had failed or were intolerant to second or third-line treatment for OAB. The primary efficacy outcome was the proportion of subjects achieving at least a 50% reduction in UUI episodes from baseline at 48 weeks post-activation. The study met its primary endpoint, with 68% (95% CI: 60-76%) of subjects reaching this threshold. Improvements were also sustained at 24 and 36 weeks, with 69% and 70% of participants achieving the ≥ 50% reduction in UUI episodes respectively. Secondary outcomes at 24 and 48 weeks demonstrated statistically significant improvements across multiple measures, including mean reductions in UUI episodes (~2.6/day), urinary urgency episodes, total voids, and nocturia. Patient-reported outcomes showed substantial improvement in symptom bother and health-related quality of life (as measured by OAB-q Questionnaire), with mean improvements of approximately 34 points on each scale by week 48 ($p < 0.001$). Adverse events related to the device or procedure were reported in 19% of implanted subjects, with 16% specifically attributable to the device. The most common adverse events were infection (7%), stimulation issues (5%), and minor wound complications. There was one serious device-related adverse event (infection) that required explantation but resolved without long term consequences. Limitations of the trial include lack of a control group or blinding, which the authors acknowledge is due to the difficulty of blinding in neuromodulation trials. The authors concluded that eCoin offers a novel, minimally invasive therapy for UUI that demonstrated durable efficacy over 12 months with minimal compliance burden, favorable safety, and high patient satisfaction (ClinicalTrials.gov NCT03556891).

National/Specialty Organizations

The **American Urological Association (AUA)** and **Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU)** published the *Guideline on the Diagnosis and Treatment of Idiopathic Overactive Bladder* (Cameron et al. 2024). The guideline emphasizes the importance of shared decision-making based on individual goals, preferences, and tolerance for side effects. Based on expert opinion and clinical principles, clinicians should discuss incontinence management strategies (e.g., pads, diapering, barrier creams) with all patients who have urgency urinary incontinence, and the guidelines strongly recommend that clinicians offer bladder training (Evidence Level: Grade A)

and other behavioral therapies to all patients with OAB.

The guideline states “Clinicians may offer minimally invasive procedures to patients with OAB who are unable or unwilling to undergo behavioral, non-invasive, or pharmacologic therapies... Clinicians are not required to mandate trials of prior therapies before offering minimally invasive procedure. Minimally invasive therapies have been associated with high success rates, durable efficacy, and excellent patient satisfaction, and offer considerable therapeutic benefits for treatment naive patients who do not want to or cannot pursue behavioral or pharmacological treatment options”. Minimally invasive therapies include sacral neuromodulation, percutaneous tibial nerve stimulation, implantable tibial nerve stimulation, or intradetrusor botulinum toxin injections (Cameron et al. 2024).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
0816T	Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (e.g., array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subcutaneous
0817T	Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (e.g., array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subfascial
0818T	Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subcutaneous
0819T	Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subfascial
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
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

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

08/27/2025 New policy. IRO review completed July 2025 by a practicing physician board-certified in Urology.

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