Regence

Medical Policy Manual Surgery, Policy No. 154

Subcutaneous Tibial Nerve Stimulation

Effective: February 1, 2025

Next Review: November 2025
Last Review: December 2024

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Subcutaneous tibial nerve stimulation (STNS) is a technique of electrical neuromodulation for the treatment of urgency urinary incontinence in patients who have failed behavioral and/or pharmacologic therapies.

MEDICAL POLICY CRITERIA

Notes:

- Stimulation of the sacral nerve as a treatment of incontinence is discussed in a separate Medical Policy (see Cross References).
- Pelvic floor stimulation as a treatment of urinary incontinence refers to electrical stimulation of the pudendal nerve and is addressed in a separate Medical Policy (see Cross References).
- This policy does not address percutaneous (non-implanted) posterior tibial nerve stimulation (PTNS) for treatment of non-neurogenic urinary dysfunction including overactive bladder, which may be considered medically necessary.

Subcutaneous tibial nerve stimulation delivered by an implantable peripheral neurostimulator system (e.g., eCoin®, Revi™) is considered **investigational** for all

indications, including individuals with non-neurogenic urinary dysfunction including overactive bladder.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence, Allied Health, Policy No. 04
2. Biofeedback, Allied Health, Policy No. 32
3. Sacral Nerve Modulation (Stimulation) for Pelvic Floor Dysfunction, Surgery, Policy No. 134

BACKGROUND

Subcutaneous tibial nerve stimulation (STNS) is an electrical neuromodulation technique for the treatment of urgency urinary incontinence in patients intolerant to, or having an inadequate response to, behavioral and/or pharmacologic therapies, or who have undergone a successful trial of percutaneous tibial nerve stimulation (PTNS).[1] STNS utilizes an implantable device to stimulate the posterior tibial nerve in a similar manner as PTNS. The posterior tibial nerve is derived from the lumbar-sacral nerves (L4-S3) which control the bladder detrusor and perineal floor. The goal of STNS and PTNS is to alter the function of the posterior tibial nerve to improve voiding function and control.[2] Voiding dysfunction includes urinary frequency, urgency, incontinence, and nonobstructive retention. Urgency symptoms and/or urge incontinence may also be referred to as overactive bladder (OAB). Common causes of voiding dysfunction are pelvic floor dysfunction (from pregnancy, childbirth, surgery, etc.), inflammation, interstitial cystitis, medication (e.g., diuretics and anticholinergics), obesity, psychogenic factors, and disease (e.g., multiple sclerosis, spinal cord injury, detrusor hyperreflexia, diabetes with peripheral nerve involvement).

STNS and PTNS were developed as less-invasive treatment alternatives to sacral nerve modulation (also called stimulation), which has been successfully used in the treatment of urinary dysfunction but requires implantation of a permanent device.[2] 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 (10mA, 1-10 Hz frequency) electrical stimulation which produces sensory and motor responses (i.e., a tickling sensation and plantar flexion or fanning of all toes).

STNS is administered through a coin-sized leadless battery-powered implant. STNS offers a less invasive alternative to traditional sacral nerve neuromodulation and offers a convenient delivery system for automated treatments without the need for chronic outpatient PTNS treatment sessions. STNS is delivered by the eCoin® Peripheral Neurostimulator System (collectively, the “eCoin® System”) and includes the eCoin® Peripheral Neurostimulator (“eCoin®”), the External Controller urgency urinary incontinence (UUI) (“External Controller”), and the Patient Controller Magnet and its components. eCoin® is a coin-sized leadless battery-powered implant that stimulates the tibial nerve (0.5-15 mA, 20 Hz frequency). The external controller is used to activate and program the eCoin® after implantation using a custom access code secured wireless protocol. The recommended treatment duration is 30 minutes every three days for the first 18 weeks (42 sessions) and every four days thereafter and is programmed by the clinician. A patient controller can be leveraged to inhibit an automatic session in the event of undesired or painful stimulation. The battery life is estimated at up to three years (range, one to eight years).[1]

REGULATORY STATUS

The eCoin® Peripheral Neurostimulator (Valencia Technologies, Inc.) received U.S. FDA premarket approval for the treatment of urgency urinary incontinence in patients intolerant to or having an inadequate response to other more conservative treatments or who have undergone a successful trial of percutaneous tibial nerve stimulation.[1]

The Revi™ System, previously referred to as the RENOVA iStim, (BlueWind Medical) received U.S. FDA PMA for the treatment of urinary incontinence with or without urinary urgency in August of 2023.

EVIDENCE SUMMARY

To isolate the specific therapeutic effects of STNS and adequately control for placebo effects and individual patient differences (clinical and demographic, known and unknown), well-designed randomized controlled trials (RCTs) that compare STNS with the current standard of care and sham treatment are needed. The RCT is the most rigorous and reliable study design for demonstrating a causal relationship between the therapy under investigation and the health outcomes of interest. The RCT study design is important to understand whether an intervention such as STNS can positively impact the health outcomes of patients with voiding dysfunction.

NON-NEUROGENIC URINARY INCONTINENCE INCLUDING OVERACTIVE BLADDER

Clinical Context and Therapy Purpose

Recommended treatments for individuals with non-neurogenic urinary incontinence, who are intolerant to or having an inadequate response to behavioral and/or pharmacologic therapies include botulinum toxin and sacral nerve modulation. Botulinum toxin is injected into the detrusor muscle. However, the toxin increases the risk of urinary retention and is not recommended for patients with a history of urinary retention or recurrent urinary tract infection (UTI). Sacral nerve modulation may be conducted in an outpatient clinical setting using temporary wire leads. Due to the incidence of lead migration, a two-step process in a surgical setting is recommended. In the initial test phase, wire leads are inserted under the skin and if 50% improvement is reported, the patient may elect permanent implantation with a pacemaker-like stimulator. If the test phase is unsuccessful, the leads are then removed. The general outcomes of interest are reductions in symptoms (e.g., self-reported assessment of symptoms, decrease in the number of voids per day) and improved quality of life.

Nonrandomized Studies

Heesakkers (2024) published a prospective, multicenter, single-arm study of the BlueWind Implantable Tibial Neuromodulation (iTNM) System.[3] One hundred and fifty one participants were implanted with the device, with 144 and 140 completing the six- and 12-month visits, respectively. At six- and 12-months post-activation, 76.4% and 78.4% of participants, respectively, experienced at least a 50% improvement in UUI episodes. 82% of participants with completed 12-month diaries were responders, with 50% classified as "dry" (on at least three consecutive diary days). No serious adverse events related to the procedure or device were reported. This study is limited by lack of a comparison group.

Lucente (2024) published two-year outcomes of the Rogers (2021) prospective, multi-center, single-arm study.[4] A three-day voiding diary was collected along with the OAB questionnaire,

Patient Global Impression of Improvement, and a custom Likert scale on subject satisfaction from 137 participants with refractory UUI. The primary endpoint was the proportion of subjects who achieved at least 50% reduction from baseline in number of UUI episodes. The primary safety measure was device-related adverse events (AEs). 72 participants completed the 96-week assessment. 78% (95% CI: 67% to 87%) experienced at least 50% reduction in UUI episodes; 48% (95% CI, 36% to 60%) experienced at least 75% reduction, and 22% (95% CI, 13% to 33%) were dry according to three-day diary self-reports. Subjects reported a decrease from baseline in their UUI episodes per day of 2.61 (SD 2.97) and 2.97 (SD 2.64) at 48 weeks and 96 weeks, respectively. Around 91.3% did not require additional medications for OAB. No serious or unanticipated AEs were reported. This study is limited by lack of a comparison group and small sample size.

Rogers (2021) evaluated the safety and efficacy of the wireless eCoin® device in a single-arm, open-label trial at 15 sites in the US.[5] 132 patients with refractory (failed one or more second- or third-line therapy) OAB received the eCoin® device and were included in the intention-to-treat analysis. The majority of patients were female (98%), and 26% had received prior PTNS therapy. At 24-week follow-up, 69% (confidence interval [CI], 61% to 77%) of patients had a 50% reduction in urge urinary incontinence symptoms based on three-day voiding diaries and were considered "responders". Results were similar at weeks 36 and 48 with 70% (CI, 62% to 78%) and 68% (CI, 60% to 76%) of patients responding, respectively. Fewer patients reported 100% reduction in symptoms, with only 21% of patients reporting 100% response at 48 weeks. By 48 weeks there was a mean decrease in urge urinary incontinence episodes (-2.61), urinary voids (-2.12), urgency episodes (-1.49), and nocturia episodes (-0.51). Outcomes were not stratified by prior treatments received. Outcomes were impacted by the COVID-19 pandemic. Pre-pandemic and in-person responder rates were 75% and 74%, respectively, whereas the responder rate during the pandemic was 60% (n=25), and the responder rate of remote visits was 57% (n=14). Adverse events related to the device or procedure were reported in 20% of patients and most were mild (11%) to moderate (6%). There were three severe adverse events, including one post-operative wound infection, one implant site infection, and one device stimulation issue. While the study met its primary performance goal of at least a 40% response rate after 48 weeks of therapy, the certainty of this data is limited by the lack of blinding and a control group and the fact that a performance goal was identified after patients had already been implanted.[1] Thus, the FDA has required the manufacturer of the eCoin® system to conduct a post-approval study to provide greater certainty of the potential benefit of the device. It is also intended to address safety concerns regarding device explantation and reimplantation following battery depletion given that the study observed the need to re-implant the device after only one year. Possible reasons for the negative impact of COVID-19 on the 48-week response rate were not explored.

A feasibility study conducted by MacDiarmid et al (2019) for the eCoin® device conducted in the U.S. and New Zealand initially enrolled 46 patients at seven sites and found reduced urge urinary incontinence episodes at three month follow-up (from 4.2 to 1.7 daily episodes; p=0.001).[6] Subsequent long-term data published in 2021 indicated continued safety and efficacy of eCoin®, with 65% of patients considered responders and 26% of responders having complete continence at 12 months and only one serious infection-related adverse event.[7] A follow-up study of 23 patients who were reimplanted with an eCoin® device after one year with a second-generation device found reimplantation to be successful with 74% and 82% of patients having at least 50% reduction in episodes of urge urinary incontinence at 12 and 24 weeks, respectively.[8] No serious device-related adverse events were reported.

There is an on-going trial, “A Prospective Study to Assess the Efficacy and Safety of the BlueWind RENOVA iStim™ System in the Treatment of Patients Diagnosed With Overactive Bladder (OASIS - OverActive Bladder StImulation System Study)”, which the FDA based their PMA approval of Revi (previously referred to as RENOVA iStim) on. There are currently no peer-reviewed publications based on this study.

PRACTICE GUIDELINE SUMMARY

AMERICAN UROLOGICAL ASSOCIATION

In 2024, the American Urological Association (AUA) and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) published updated guidelines on the diagnosis and treatment of idiopathic overactive bladder.[9] PTNS is mentioned as a minimally invasive therapy option. The guideline states that "Clinicians may offer minimally invasive procedures to patients who are unable or unwilling to undergo behavioral, non-invasive, or pharmacologic therapies (Clinical Principle)" and " Clinicians may offer patients with OAB, in the context of shared decision making, minimally invasive therapies without requiring trials of behavioral, non-invasive, or pharmacologic management (Expert Opinion)" This clinical practice guideline does not address STNS.

AMERICAN COLLEGE of OBSTETRICIANS AND GYNECOLOGISTS

In 2015, the American College of Obstetricians and Gynecologists practice bulletin on the treatment of urinary incontinence in women did not address STNS or other types of nerve stimulation.[10]

SUMMARY

There is not enough research to show that subcutaneous tibial nerve stimulation (STNS) improves health outcomes for any indication, including but not limited to non-neurogenic urinary incontinence. No clinical guidelines based on research recommend STNS. Therefore, STNS is considered investigational for all indications, including but not limited to non-neurogenic urinary incontinence.

REFERENCES

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CODES

NOTE: CPT codes for percutaneous implantation of neurostimulator electrodes (i.e., 64553, 64555, 64561, 64590) are not appropriate since PTNS uses percutaneously temporarily inserted needles and wires rather than percutaneously implanted electrodes that are left in place.

Codes	Number	Description
CPT	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
	0817T	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; 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
HCPCS	None	

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