

Care N' Care Insurance Company of North Carolina, Inc.
POLICY

Medical Policy Tibial Nerve Stimulation for Bladder and Bowel Control			
Department Responsible Utilization Management	Policy Code 10.0	Effective Date 10/1/2026	Next Review Date 8/19/2027
Title of Person Responsible Medical Director	Approval Council CNC-NC Medical Oversight Committee		Approved Date 8/19/2027

PURPOSE

This policy addresses medical necessity for tibial nerve stimulation (TNS) in individuals with urinary retention, chronic urinary incontinence and chronic fecal incontinence.

Key Information

Tibial nerve stimulation is a treatment used for bladder and bowel control problems. It works by sending small electrical pulses to a nerve near the ankle (the tibial nerve) that connects to the bladder. There are three ways this treatment is given: percutaneous tibial nerve stimulation (PTNS), where a needle is placed under the skin; implantable tibial nerve stimulation, which uses a small device placed under the skin near the ankle; and transcutaneous tibial nerve stimulation (TTNS), which sends the pulses through patches on the skin. PTNS and implantable TNS can be used for urinary urge incontinence, urinary urgency or frequency, urinary retention, and fecal incontinence that have not improved with other treatments like medication or exercises. TTNS has also been studied for these conditions, as well as for other health issues, but it has not been shown to work as well or as consistently. All methods aim to improve symptoms by calming the nerves that control the bladder or bowel.

What the Studies Show

PTNS has been shown in several studies to help people with overactive bladder or urinary incontinence. It often reduces the number of times a person needs to urinate, the number of accidents, and the amount of leakage. Some studies compared PTNS to medications and found similar results, though the studies had limitations, such as small numbers of people and short follow-up. In one long-term study, 97% of people said their symptoms improved over 3 years, though many people dropped out before the study ended. Studies of implantable TNS showed that most people had fewer symptoms after getting the device and the effects lasted at least 1 to 2 years. Some people had mild side effects like pain, but serious problems were rare. TTNS has been studied but results are mixed. Some studies showed benefit, but others did not. The studies were small and used different methods, so it is hard to know how well TTNS really works. For fecal incontinence, PTNS may help some people, but better studies are needed to know if it improves health. TTNS has not shown reliable benefit for this use. TTNS has also been tested for problems like constipation and sexual function, but these uses are not supported by high-quality research.

When is Tibial Nerve Stimulation Clinically Appropriate?

Tibial nerve stimulation (PTNS or implantable TNS) may be appropriate in these situations:

- The person has had urinary urge incontinence, urgency/frequency, or non-obstructive urinary retention for at least 3 months; **and**

- The condition is not due to a nerve problem; **and**
- The symptoms are severe enough to affect daily life; **and**
- The person tried other treatments (like medications or exercises) for 2 to 3 months and they did not work or caused side effects; **and**
- For ongoing treatment after a 12-week trial, there was at least a 50% improvement in symptoms such as fewer accidents, fewer bathroom trips, or better bladder emptying; **and**
- The problem continues and the person is still getting benefit from the treatment.

An implantable tibial nerve stimulator may be used if the person has met all the above conditions and had a successful trial with PTNS (with at least 50% symptom improvement).

Replacing or revising a tibial nerve stimulator may be appropriate when:

- The treatment helped, **and**
- The device has stopped working right **or**
- There are problems like infection or pain at the implant site.

Removing a device may be appropriate when:

- It no longer works; **or**
- It does not help the person's symptoms; **or**
- There are problems like infection or pain.

What is Not Clinically Appropriate?

The following have not been proven to improve health and are not considered clinically appropriate:

- PTNS or implantable TNS when the required conditions above are not met. Unnecessary or unproven treatments can lead to confusion, needless worry, or treatment that does not help.
- Replacement, revision, or removal of devices when the needed criteria are not met.
- TTNS for any condition, including bladder or bowel problems. Better studies are needed to know if it improves health. Results of available research are mixed or weak, and no major medical groups currently recommend TTNS.

DEFINITIONS, INITIALS, ACRONYMS

PTNS- percutaneous tibial nerve stimulation

TNS – tibial nerve stimulation

TTNS- transcutaneous tibial nerve stimulation

POLICY

Medically Necessary:

An initial 12-week trial of *percutaneous* tibial nerve stimulation is considered **medically necessary** when the following criteria are met (*A and B*):

- Any of the following are present for at least 3 months, and not due to a neurological condition:
 - Urinary urge incontinence; **or**
 - Urinary urgency/frequency; **or**
 - Non-obstructive urinary retention; **and**
- Criteria 1 *and* 2 below are met:

1. Clinically significant symptoms are present (for example, frequency, or severity impacts ability to work or participate in activities outside of the home); **and**
2. Symptoms are refractory to, or individual could not tolerate, conservative treatment (for example, medication, pelvic floor muscle exercises, pelvic floor physical exercises with biofeedback, bladder training, or intermittent catheterizations for non-obstructive urinary retention) for at least a sufficient duration to fully assess treatment effect.*

* **Note:** The time frame for prior conservative treatment measures to demonstrate a refractory response is generally considered to be 2 to 3 months' duration, subject to individual variability.

Continuation of *percutaneous* tibial nerve stimulation with monthly treatment is considered **medically necessary** when the following criteria are met (A and B):

- A. An initial 12-week trial demonstrated improved urinary dysfunction meeting treatment goals, defined as:
 1. For urinary urge incontinence: At least 50% reduction in one of the following: daily incontinence episodes, severity of the episodes, or the number of pads/diapers used per day; **or**
 2. For urinary urgency/frequency: At least 50% reduction in the number of voids daily, or 50% increase in volume voided per void; **or**
 3. For urinary retention: At least a 50% reduction in catheter volume/catheterization; **and**
- B. Annual evaluation indicates that the condition for which the treatment was initiated is still present.

An *implantable* tibial nerve stimulator is considered **medically necessary** for individuals when the following criteria are met (A and B):

- A. The individual has met criteria above for evaluation for a temporary percutaneous tibial nerve stimulator; **and**
- B. The individual has demonstrated a successful response to a 12-week trial of percutaneous tibial nerve stimulation defined as:
 1. For urinary urge incontinence: At least 50% reduction in one of the following: daily incontinence episodes, severity of the episodes or the number of pads/diapers used per day; **or**
 2. For urinary urgency/frequency: At least 50% reduction in the number of voids daily, or 50% increase in volume voided per void; **or**
 3. For urinary retention: At least a 50% reduction in catheter volume/catheterization.

Replacement or revision of a percutaneous or implantable tibial nerve stimulator (with or without lead changes) is considered **medically necessary** when the following have been met:

- A. The individual has demonstrated clinical benefit from tibial nerve stimulation; **and**
- B. The current implanted device is no longer functioning appropriately; **or**
- C. There are complications such as, but not limited to, infection or implant site pain.

Removal of an implanted tibial nerve stimulator is considered **medically necessary** when any of the following have been met:

- A. The device is no longer functioning appropriately; **or**
- B. The device has been determined to be an ineffective treatment for the individual's symptoms; **or**
- C. There are complications such as, but not limited to, infection or implant site pain.

Not Medically Necessary:

Percutaneous or implantable tibial nerve stimulation is considered **not medically necessary** when the medically necessary criteria above have not been met, including for chronic fecal incontinence.

Replacement, revision, or removal of a percutaneous or implantable tibial nerve stimulator is considered **not medically necessary** when the medically necessary criteria above for replacement or revision have not been met.

Transcutaneous tibial nerve stimulation, including tibial nerve neuromodulation, is considered **not medically necessary** for all indications.

CODING

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:**CPT**

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
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
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

ICD-10 Diagnosis

N32.81	Overactive bladder
N39.41-N39.498	Other specified urinary incontinence

R33.0-R33.9	Retention of urine
R35.0-R35.89	Polyuria
R39.11-R39.198	Other difficulties with micturition

When services are not medically necessary:

For the procedure and diagnosis codes listed above when criteria are not met or for all other diagnoses not listed.

When services are also not medically necessary:

For the following procedure codes, or when the code describes a procedure or device designated in the Clinical Indications section as not medically necessary.

CPT

0988T	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 and subfascial
0989T	Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subcutaneous and subfascial

HCPCS

A4545	Supplies and accessories for external tibial nerve stimulator (e.g., socks, gel pads, electrodes, etc.), needed for one month [e.g., supplies for Vivally and ZIDA systems]
E0736	Transcutaneous tibial nerve stimulator [e.g., ZIDA Wearable Neuromodulation control unit, Vivally System with hardware control unit]
E0737	Transcutaneous tibial nerve stimulator, controlled by phone application [e.g., Vivally System, smartphone]

ICD-10 Diagnosis

All diagnoses

RESPONSIBILITIES

The CNC-NC Utilization Management Department has day-to-day responsibility for the operationalization policy and procedures associated with organization determinations for tibial nerve stimulation, and to ensure that the policy is consistently applied in a uniform manner.

The CNC-NC Medical Oversight Committee is responsible to ensure that appropriate medical management and quality standards are established and adhered to promote effective and compliant member care.

The CNC-NC Board of Directors have overarching responsibility for review and approval of this policy, and it complies with all applicable federal and state laws, regulations and sub-regulatory guidance.

REFERENCE DOCUMENTS/LINKS

Peripheral tibial nerve stimulation (PTNS) is a **safe and effective guideline-recommended therapy** for urge urinary incontinence (UUI), with a **pooled success rate of approximately 68%** and efficacy **comparable to anticholinergic medications** but with significantly fewer adverse effects. [1-2] It is considered a third-line treatment option for patients who have not responded adequately to behavioral therapy and pharmacotherapy.

Efficacy Data

A systematic review and meta-analysis of 28 studies (2,461 patients) demonstrated significant reductions across all key OAB/UUI metrics: [1]

- Incontinence episodes per day: **-1.37** (95% CI -1.71 to -1.02, $p < 0.001$)
- Voiding frequency per day: -2.48 ($p < 0.001$)
- Nocturia frequency per day: -1.57 ($p < 0.001$)
- Urgency episodes per day: -2.20 ($p = 0.006$)
- Maximum cystometric capacity: +63.76 mL ($p < 0.001$)

In a real-world cohort, 86% of patients reported symptom improvement, with incontinence episodes decreasing by **79.6%** (from 1.6 to 0.4 episodes/day, $p < 0.001$). [3]

Comparative Effectiveness

- PTNS demonstrates **superior efficacy to sham** treatment, with large effect sizes in meta-analyses. [4-5]
- PTNS is **as effective as antimuscarinic agents** for micturition frequency, nocturia, urge incontinence, and voided volume, but with significantly lower discontinuation rates and fewer adverse events ($p = 0.003$ and $p = 0.0001$, respectively). [2]
- Among nonimplantable electrical stimulation modalities, percutaneous tibial stimulation was ranked as the **most effective** for symptom severity reduction (SMD -1.86). [6]
- Tibial neurostimulation showed better results than sacral neurostimulation for urge incontinence in one meta-analysis, though sacral neuromodulation (SNM) may have superior long-term durability. [7-8]

The following forest plot from an umbrella review illustrates the effect of PTNS on urinary incontinence across different comparisons:

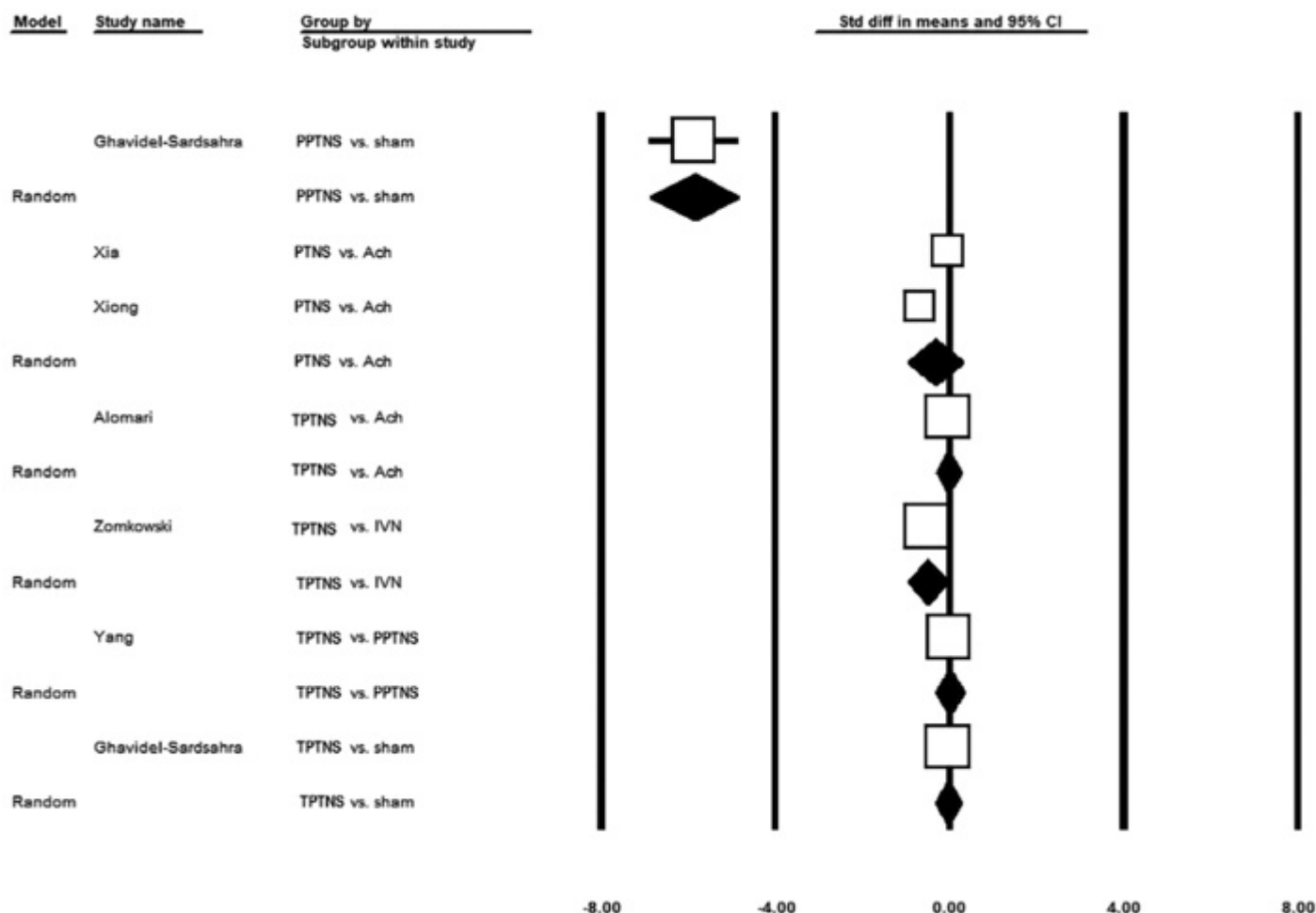


Figure 3. The analysis of urinary incontinence.

[Effects of posterior tibial nerve stimulation \(PTNS\) on lower urinary tract dysfunction: An umbrella review.](#) Neurourol Urodyn. January 31, 2024.

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Protocol and Practical Considerations

A standard course involves **30-minute sessions once weekly for 8–12 weeks**, delivered via a fine-gauge needle near the posterior tibial nerve at the ankle. [9] Key practical points include:

- **Maintenance therapy is required** — the effect is relatively short-lived, and ongoing periodic treatments are needed to sustain benefit. [4][9]
- The burden of weekly office visits limits patient compliance; insurance may cover only a limited number of lifetime visits. [4]
- PTNS does **not increase post-void residual volume**, distinguishing it from anticholinergics. [9]
- Adverse effects are minimal, primarily limited to mild pain at the puncture site. [1]
- MRI compatibility is preserved (no metallic implant). [9]

Emerging Implantable Devices

To address the compliance limitations of percutaneous PTNS, **implantable tibial nerve stimulation devices** have been developed, with at least two FDA-authorized devices now available. These deliver the same mechanism of action via a permanent implant enabling at-home stimulation, eliminating the need for repeated office visits. [4]

Neurogenic Populations

PTNS has also shown benefit in neurogenic OAB, including patients with multiple sclerosis, Parkinson's disease, and post-stroke urgency incontinence, though the need for repeated office visits can be particularly burdensome in these populations. Transcutaneous tibial nerve stimulation (TTNS) offers a home-based alternative for these patients. [9]

1. [Percutaneous Tibial Nerve Stimulation for Overactive Bladder Syndrome: A Systematic Review and Meta-Analysis.](#)

International Urogynecology Journal. 2020. Wang M, Jian Z, Ma Y, et al.SR

2. [Pooled Analysis of the Efficacy and Safety of Tibial Nerve Stimulation Versus Antimuscarinic Agents in the Management of Overactive Bladder Syndrome.](#)

Medicine. 2021. Xia L, Yan H, Sun Y, et al.SR

3. [Efficacy of Percutaneous Tibial Nerve Stimulation for Overactive Bladder in Women and Men at a Safety Net Hospital.](#)

The Journal of Urology. 2020. Jiang JF, Leung AK, Pettitt-Schieber B, et al.

4. [Tibial Nerve Stimulation for Urge Urinary Incontinence and Overactive Bladder: Narrative Review of Randomized Controlled Trials and Applicability to Implantable Devices.](#)

Advances in Therapy. 2024. Lee UJ, MacDiarmid S, Matthews CA, Gillespie E, Peters KM.Review

5. [Effects of posterior tibial nerve stimulation \(PTNS\) on lower urinary tract dysfunction: An umbrella review.](#)

Neurourology and Urodynamics. 2024. Tahmasbi F, Salehi-Pourmehr H, Naseri A, et al.SR

6. [Comparison of Nonimplantable Electrical Stimulation in Women With Urinary Incontinence: A Systematic Review and Network Meta-Analysis of Randomized Controlled Trials.](#)

Scientific Reports. 2024. Yu TY, Yu CY, Escorpizo R, et al.SR

7. [The Effectiveness of Different Electrical Nerve Stimulation Protocols for Treating Adults With Non-Neurogenic Overactive Bladder: A Systematic Review and Meta-Analysis.](#)

International Urogynecology Journal. 2022. Zomkowski K, Kammers I, Back BBH, et al.SR

8. [Efficacy and Safety of Sacral and Percutaneous Tibial Neuromodulation in Non-Neurogenic Lower Urinary Tract Dysfunction and Chronic Pelvic Pain: A Systematic Review of the Literature.](#)

European Urology. 2018. Tutolo M, Ammirati E, Heesakkers J, et al.Review

9. [Lower Urinary Tract Dysfunction in the Neurological Patient: Clinical Assessment and Management.](#)

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PREVIOUS REVISION/REVIEW DATES

Date	Reviewed	Revised	Notes
06/09/2026			This is a new policy.
8/19/2026	X		Reviewed and approved by HTA/Cone Medical Oversight Committee
