

Medical Policy
Neuromodulation for Overactive Bladder

Document Number: 008

	Commercial Health Connector/Qualified Health Plans	MassHealth
Authorization required Percutaneous Tibial Nerve Stimulation (PTNS) Sacral Nerve Stimulation (SNS) including: Two testing options prior to permanent implantation: <ul style="list-style-type: none"> ▪ Percutaneous Nerve Evaluation (PNE) ▪ Stage 1 Testing Permanent implantation Note: Each test requires separate authorizations	X	X
No notification or authorization		
Not covered		

Overview

The purpose of this document is to describe the guidelines AllWays Health Partners utilizes to determine medical appropriateness for neuromodulation, including percutaneous tibial nerve stimulation (PTNS), trial of sacral nerve neuromodulation, and permanent implantation of sacral nerve stimulation (SNS).

Coverage Guidelines

AllWays Health Partners covers neuromodulation for the treatment of overactive bladder (OAB) when such treatment is recommended by the member’s primary care physician or treating specialist, meets the medical necessity criteria indicated below, and is authorized prior to the procedure.

Percutaneous Tibial Nerve Stimulation

Initial Treatment Assessment with PTNS

For the initial PTNS assessment, AllWays Health Partners covers a single 12-week trial of PTNS for the treatment of overactive bladder syndrome including urge incontinence and urgency frequency when all the following criteria are met:

1. The member is 18 years of age or older;
2. The member has been diagnosed with OAB unrelated to a neurological condition with a thorough history, exam and appropriate testing when indicated;
3. The provider has a well-documented and detailed symptom diary in order to gauge treatment outcomes;
4. The member has contraindications to, or is refractory to conservative therapy including all of the following:
 - a. Behavioral training such as: habit training, prompted voiding, routine/scheduled toileting, fluid management, and pelvic floor exercise for 6 months;

- b. At least 2 oral antimuscarinic medications taken for at least 4 weeks followed by a failed trial on an oral β_3 -adrenoreceptor agonist, e.g. Mirabegron¹; and
5. Urge incontinence or urge frequency has resulted in significant disability to the member such that the frequency and/or severity of symptoms have resulted in limited activities of daily living.
6. The member is willing and able to comply and has the cognitive capacity to participate with the treatment protocol during the testing phases. This is evidenced through the treating provider's medical notes.

Maintenance Treatment with PTNS

If the member has shown successful treatment of PTNS during the 12-week trial, a maximum of 26 treatments per initial 12-month period and maximum of 12-13 treatments per subsequent 12-month period is covered. Successful treatment of PTNS is demonstrated when:

1. There is greater than 50% symptom relief of: number of daily episodes, severity of episodes and/or numbers of pads/diapers used, that is well documented in voiding diaries during the initial treatment phase.
2. The member is willing and able to comply and has the cognitive capacity to participate with the treatment protocol during the maintenance phases. This is evidenced through the treating provider's medical notes.

Exclusions

AllWays Health Partners does not provide coverage for PTNS in the following instances:

1. The member is under the age of 18.
2. Member who is incontinent due to mechanical obstruction, stress incontinence or neurologic disease origin.
3. A member has a condition such that PTNS is medically contraindicated. PTNS is contraindicated in patients who:
 - a. Have pacemakers;
 - b. Have implantable defibrillators;
 - c. Are pregnant or who plan to become pregnant during the duration of treatment.
4. Maintenance PTNS when initial treatment regimen failed. A failed treatment regimen is defined by less than 50% decrease in symptoms.
5. The member is unwilling or unable to comply with the treatment protocol and does not have the cognitive capacity to participate with the treatment protocol during the initial treatment and maintenance phases.

Sacral Nerve Stimulation (SNS)

SNS always involves a two-step process. To be eligible for the first step members must meet criteria for PTNS eligibility and have exhausted non-surgical measures before moving on to SNS.

The first step is done with a temporary electrode to determine if SNS reduces the symptoms of OAB. This step can be done by one of two procedures. Clinicians insert an electrode into the sacral nerve in an office-

¹ Botox is covered by AllWays Health Partners for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency in adults when pharmacy criteria are met, and it is authorized by AllWays Health Partners. 399 Revolution Drive, Suite 810, Somerville, MA 02145 | allwayshealthpartners.org



based procedure, percutaneous nerve evaluation (PNE), or under anesthesia during day surgery, Stage 1 Testing for SNS.

Initial Testing/Trial Period of SNS

AllWays Health Partners covers a one lifetime 3–14-day trial of sacral nerve stimulation, through two different types of tests:

- PNE²; or
- Stage 1 Testing

A member must meet the following criteria to be eligible for SNS testing:

1. The member is 18 years of age or older;
2. The member has been diagnosed with OAB or non-obstructive urinary retention unrelated to a neurological condition with a thorough history, exam, and appropriate testing if indicated;
3. The provider has a well-documented and detailed symptom diary in order to gauge treatment outcomes;
4. The member has contraindications to, intolerance or is refractory to conservative therapy including all of the following:
 - a. Behavioral training such as: habit training, prompted voiding, routine/scheduled toileting, fluid management and pelvic floor exercise for 6 months;
 - b. At least 2 oral medications taken for at least 4 weeks (antimuscarinics, β -3-adrenoreceptor agonist, e.g. Mirabegron);
5. Urge incontinence or urge frequency has resulted in significant disability to the member such that the frequency and/or severity of symptoms have resulted in limited activities of daily living; and;
6. The member is an appropriate surgical candidate for the permanent implantation. A test/trial period of SNS is contraindicated in patients who:
 - a. Have pacemakers;
 - b. Have implantable defibrillators;
 - c. Are pregnant or who plan to become pregnant during the duration of treatment.
7. The member is willing and able to comply with the treatment protocol and has the cognitive capacity to use the remote control to optimize device function during the testing and treatment phases.

Permanent Implantation of SNS

AllWays Health Partners covers one lifetime permanent implantation of a SNS device when all the following criteria are met:

1. The member has shown successful treatment during the SNS Test/Trial Period. Successful treatment is demonstrated by a greater than 50% of symptom relief of: number of daily episodes,

²AllWays Health Partners may cover a stage 1 of a Two-Stage Tined Lead Procedure after a PNE that is inconclusive due to dislodgment. During the course of the staged implant, each stage of the procedure may be authorized only once, unless there are extraordinary clinical circumstances requiring replacement of the leads. The medical necessity for the latter must be documented in the medical record.



severity of episodes and/or numbers of pads/diapers used, that is well documented in voiding diaries during the SNS Test/Trial Period.

2. The member is willing and able to comply with the treatment protocol and has the cognitive capacity to use the remote control to optimize device function.

Note: AllWays Health Partners will authorize the replacement of the power supply of the permanent device when needed.

Note: Lifetime requirement does not include timed lead revision/battery replacement.

Exclusions

AllWays Health Partners does not provide coverage for Sacral Nerve Stimulation – Test/Trial or Permanent Implantation in the following instances:

1. A member has a condition such that SNS is medically contraindicated. SNS is contraindicated in members who:
 - a. Have pacemakers;
 - b. Have implantable defibrillators;
 - c. Are pregnant or who plan to become pregnant during the duration of treatment.
2. The member is under the age of 18.
3. Member who has urinary incontinence due to mechanical obstruction, stress incontinence, or neurologic disease origin.
4. The use of the implantable sacral nerve stimulation (including associated testing) when used with a member who is unwilling or unable to comply with the treatment protocol and/or does not have the cognitive capacity to use the remote control to optimize device function during the testing and treatment phases.

Definitions

Behavioral Training: A diverse group of interventions that improve urinary incontinence by changing a person's bladder habits and teaching new skills. These interventions can be used alone, in combination with each other, or as an adjunct to medication therapy.

Overactive Bladder: Overactive Bladder (OAB) is the chronic condition associated with urinary urgency with or without urge incontinence and increased frequency.

Urinary Urgency: Uncontrollable urge to urinate.

Urge Incontinence: Involuntary leakage when there is a strong urge to void.

Increased Frequency: Voiding too often during the day.

Percutaneous Nerve Evaluation (PNE): Percutaneous Nerve Evaluation, also called percutaneous nerve stimulation, is a type of test that may be done prior to implantation of the permanent SNS device. During this outpatient procedure, a test needle is used to identify the appropriate sacral nerve. Once identified, a temporary electrode wire is placed in the patient (under local anesthesia) through the left or right S3 sacral foramen. The wire is secured with tape and connected to an external generator (stimulator) the patient wears for a trial period typically lasting three to seven days. Generally, at a minimum, a 50%

improvement in one or more of the primary symptoms must be documented before a permanent stimulator can be implanted.

Percutaneous Tibial Nerve Stimulation (PTNS): Percutaneous Tibial Nerve Stimulation, also known as posterior tibial nerve stimulation, as well as peripheral tibial nerve stimulation, is a type of neuromodulation, which is less invasive than the alternative SNS. A slim needle electrode is inserted near the ankle. The needle electrode is then connected to the battery-powered stimulator. During treatment, mild impulses from the stimulator travel through the needle electrode along the posterior tibial nerve and to the sacral plexus, the nerves in the pelvic that controls bladder function. The exact mechanism of action is not precisely understood.

Percutaneous Tibial Nerve Stimulation Initial Treatment Regimen: A treatment regimen for PTNS is defined as 30-minute sessions given weekly for 12 weeks.

Sacral Nerve Stimulation (SNS): Sacral Nerve Stimulation (SNS), also known as sacral neuromodulation, is defined as the implantation of a permanent device (a pulse generator) that modulates the neural pathways controlling bladder function. A surgeon implants the small device under the skin, usually above the buttock. Attached to the device is a thin, electrode-tipped wire that carries controlled electrical impulses to the sacral nerves. Two external components of the system help control the electrical stimulation; a control magnet that the patient uses to turn the device on and off, and a device that allows programming and adjustments.

Two-Stage Tined Lead Procedure for Sacral Nerve Stimulation: A type of test that may be done prior to implantation of the permanent SNS device (this test is used in the initial testing/trial phase). In the first stage, a tined lead is implanted. The tined lead has an insulated electrical conductor with one end electrically connected to a pulse generator. The testing phase can last as long as a few weeks, and if patients show a 50% or greater reduction in symptom frequency, the treating physician can proceed to stage two, which is the permanent implantation of the SNS device.

Urinary Retention: The inability to completely empty the bladder during urination.

CPT/HCPC Codes

Authorized CPT/HCPCS Codes	Code Description
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming
64581	Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
A4290	Sacral nerve stimulation test lead, each

Effective

April 2018: Annual Review

February 2017: Effective date

References

Rovner E. Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults: AUA/SUFU Guideline. *Yearbook of Urology* 2014;2013:47–8.

Chapple C, Sievert KD, MacDiarmid S, et al. OnabotulinumtoxinA 100 U significantly improves all idiopathic overactive bladder symptoms and quality of life in patients with overactive bladder and urinary incontinence: a randomized, double-blind, placebo-controlled trial. *Eur Urol.* 2013;64(2):249-256

Gaziev et al. Percutaneous tibial nerve stimulation (PTNS) efficacy in the treatment of lower urinary tract dysfunctions: a systematic review. *BMC Urology* 2013, 13:61

Gormley E, Lightner D, Burgio K, et al. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU guideline. *J Urol* 2015;193:1572-1580

Hayes Medical Technology, Medical Technology Directory, Percutaneous tibial nerve stimulation for the treatment of lower urinary tract dysfunction. November 19, 2015. Accessed 2016

Hayes Medical Technology, Health directory, Implantable sacral nerve stimulation for urinary voiding dysfunction. July 12, 2010. Accessed 2012.

MacDiarmid, S., Peters, K., et. al. Long-term durability of percutaneous tibial nerve stimulation for the treatment of overactive bladder. *The Journal of Urology.* Vol 183; Jan 2010. National Coverage Determinations (LCD) for Sacral Nerve Stimulation For Urinary Incontinence (230.18)

National Coverage Determinations (LCD) Percutaneous Tibial Nerve Stimulation (PTNS) L31523

Nitti VW, Dmochowski R, Herschorn S, et al.; EMBARK Study Group. OnabotulinumtoxinA for the treatment of patients with overactive bladder and urinary incontinence: results of a phase 3, randomized, placebo-controlled trial. *J Urol.* 2013;189(6):2186-2193.

Tincello DG, Rashid T, Revicky V. Emerging treatments for overactive bladder: clinical potential of botulinum toxins. *Research and Reports in Urology* 2014;6:51-57. doi:10.2147/RRU.S44665.

University of Texas at Austin, School of Nursing, Family Nurse Practitioner Program. Recommendations for the management of urge urinary incontinence in women. Austin (TX): University of Texas at Austin, School of Nursing; May 2010. P9:

Walsh, J. Percutaneous tibial nerve stimulation for the treatment of overactive bladder. California Technology Assessment Forum. June 2012.

Wyman, JF, Burgio, KL, Newman, DK. Practical aspects of lifestyle modifications and behavioral interventions in the treatment of overactive bladder and urgency urinary incontinence. *International Journal of Clinical Practice.* 2009;63(8):1177–1191. doi:10.1111/j.1742-1241.2009.02078.x

Wyman, J. Behavioral interventions for the patient with overactive bladder. *J WOCN* 2005;32