Mass General Brigham
Health Plan

Medical Policy
Neuromodulation for Overactive Bladder and Fecal Incontinence

Policy Number: 036

	Commercial and Qualified Health Plans	Mass General Brigham ACO	Medicare Advantage	OneCare	Senior Care Options (SCO)
Authorization required Percutaneous Tibial Nerve Stimulation (PTNS) Sacral Nerve Stimulation (SNS) including: Two testing options prior to permanent implantation: ▪ Percutaneous Nerve Evaluation (PNE) ▪ Stage 1 Testing Permanent implantation Note: Each test requires separate authorizations	X	X	X	X	X
No notification or authorization					
Not payable		X (A4290)			

Overview

The purpose of this document is to describe the guidelines Mass General Brigham Health Plan 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) as treatment for overactive bladder and fecal incontinence. These criteria are also available through a custom subset accessible in InterQual®. To access the subset, log into Mass General Brigham Health Plan's provider website at MassGeneralBrighamHealthPlan.org and click the InterQual® Criteria Lookup link under the Resources Menu.

Coverage Guidelines

Mass General Brigham Health Plan covers neuromodulation for the treatment of overactive bladder (OAB) and fecal incontinence 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

Overactive Bladder

Initial Treatment Assessment with PTNS

For the initial PTNS assessment, Mass General Brigham Health Plan 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; and

2. The member has been diagnosed with OAB unrelated to a neurological condition with a thorough history, exam and appropriate testing when indicated; and

3. The provider has a well-documented and detailed symptom diary in order to gauge treatment outcomes; and

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 3 months; and

    b. Has failed, has a contraindication to or has been intolerant of at least 2 oral medications taken for at least 4 weeks (antimuscarinics, β-3-adrenoreceptor agonist, e.g., Mirabegron[1]); 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; and

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

Mass General Brigham Health Plan 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.

[1] Botox is covered by Mass General Brigham Health Plan 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 Mass General Brigham Health Plan or affiliates.

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.

6. The member is unable to tolerate any conservative medical or behavioral therapy.

Sacral Nerve Stimulation (SNS)
Overactive Bladder
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-based procedure, percutaneous nerve evaluation (PNE), or under anesthesia during day surgery, Stage 1 Testing for SNS.

Initial Testing/Trial Period of SNS
Mass General Brigham Health Plan covers a 3–14-day trial of sacral nerve stimulation, through two different types of tests:

- PNE[2]; 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; and
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; and
3. The provider has a well-documented and detailed symptom diary in order to gauge treatment outcomes; and
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; and
    b. At least 2 oral medications taken for at least 4 weeks (antimuscarinics, β-3-adrenoreceptor agonist, e.g., Mirabegron); 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; 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; and/or
    b. Have implantable defibrillators; and/or

[2]Mass General Brigham Health Plan may cover a stage 1 of a Two-Staged 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.

c. Are pregnant or who plan to become pregnant during the duration of treatment; and

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

Mass General Brigham Health Plan 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 greater than or equal to 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 SNS Test/Trial Period; and

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: Mass General Brigham Health Plan will authorize the replacement of the power supply of the permanent device when needed.

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

Exclusions

Mass General Brigham Health Plan 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.

Fecal Incontinence

Initial Trial Phase of Implanted SNS

A screening trial of sacral nerve stimulation (SNS) with an external stimulator for either percutaneous nerve evaluation (PNE) or an implanted lead is considered medically necessary for the treatment of a diagnosis of fecal incontinence when ALL of the following criteria are met:

1. The member is/has been experiencing chronic fecal incontinence with greater than 2 incontinent episodes on average per week with duration greater than 6 months or more for at least 12 months after vaginal childbirth.

2. The member is an appropriate candidate for surgery.

3. There is documented failure, intolerance, or contraindication to conservative medical management (e.g., dietary management, pharmacotherapy, biofeedback, pelvic floor retraining)
4. There is no significant anorectal malformation or chronic inflammatory bowel disease involving the anus.
5. The condition is not related to chronic inflammatory bowel disease, chronic pelvic pain, or constipation;
6. The incontinence is not related to a neurologic condition such as peripheral neuropathy or complete spinal cord injury.

Permanent Implantation of SNS

Permanent SNS implantation for fecal incontinence is considered medically necessary when there has been a beneficial clinical response to a screening trial of SNS as evidenced by at least a 50% improvement in reported symptoms.

Mass General Brigham Health Plan considers sacral nerve stimulation for fecal incontinence experimental and investigational when these criteria are not met.

Medicare Variation

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for medical necessity determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs), and documentation included in the Medicare manuals are the basis for medical necessity determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies are used for medical necessity determinations. **At the time of Mass General Brigham Health Plan's most recent policy review, Medicare includes coverage guidelines for the following:**

- **LCD: Posterior Tibial Nerve Stimulation for Voiding Dysfunction (L33396)**
- **LCD: Sacral Nerve Stimulation for the Treatment of Urinary and Fecal Incontinence (L39543)**
- **NCD: Sacral Nerve Stimulation for Urinary Incontinence (230.18)**

When a provider for a Medicare Advantage member requests SNS that is not for the treatment of urinary incontinence, or requests PTNS, and that provider is located outside of the jurisdictions in which the LCDs above apply, Mass General Brigham Health Plan uses internal criteria (as described in this policy) to determine medical necessity.

MassHealth Variation

Mass General Brigham Health Plan uses guidance from MassHealth for medical necessity determinations for its Mass General Brigham ACO members. When there is no guidance from MassHealth for the requested service, Mass General Brigham Health Plan's medical policies are used for medical necessity determinations. **At the time of Mass General Brigham Health Plan's most recent policy review, MassHealth did not have any medical necessity guidance for neuromodulation for overactive bladder or fecal incontinence.**

OneCare and SCO Variation

Mass General Brigham Health Plan uses guidance from CMS for medical necessity determinations for its OneCare and SCO plan members. NCDs, LCDs, LCAs, and documentation included in the Medicare manuals are the basis for medical necessity determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan uses medical necessity guidelines from MassHealth. When there is no guidance from CMS or from MassHealth, Mass General Brigham Health Plan's medical policies are used for medical necessity determinations.

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.

Fecal Incontinence: The inability to control bowel movements leading to feces leaking from the rectum.

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.

Codes

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

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)
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
A4290	Sacral nerve stimulation test lead, each

Summaries of Evidence

Sacral Nerve Stimulation

The pivotal trial for SNS was the InSite for OAB trial, a prospective multicenter RCT comparing SNS to standard medical therapy for patients with OAB, urinary frequency, and urinary incontinence despite treatment with at least 1 anticholinergic medication (Siegel et al. 2015). In the intention-to-treat (ITT) analysis, 61% of patients in the treatment group, and 42% in the control group, had treatment success, defined as either a return to normal voiding frequency or a >50% decrease in leaks by 6 months (p=0.02). This difference was still larger in the as-treated analysis. Quality of life improved more in the treatment group than in the control group. Adverse event rates were similar in the two groups. These improvements were sustained in five-year follow up (Siegel et al. 2018).

Percutaneous Tibial Nerve Stimulation

The most recent AUA/SUFU guideline on overactive bladder makes a moderate recommendation with grade A evidence that SNS, PTNS, and/or intradetrusor botulinum toxin injection should be offered to patients who have an inadequate response to, or have experienced intolerable side effects from, pharmacotherapy or behavioral therapy (Cameron et al. 2024).

Effective Dates

January 2026: Ad hoc review. Updated prior authorization table and added variation for OneCare and SCO members.
September 2025: Ad hoc review. Summary of evidence added. Code disclaimer and references updated.
March 2025: Annual review. LCD added. Prior authorization table at top of policy fixed.
February 2025: Ad hoc review. Codes updated. Added reference to custom InterQual® subset.
December 2024: Ad hoc review. Added MassHealth variation language.
March 2024: Annual review.
March 2023: Annual review. Medicare Advantage added to table. Added Medicare variation language. References updated.
April 2022: Annual review. Under Percutaneous Tibial Nerve Stimulation, added exclusion “The member is unable to tolerate any conservative medical or behavioral therapy”. Under Initial Testing/Trial Period of SNS, removed criteria restricting trial to one lifetime. Added Fecal Incontinence criteria. Under Definitions, Added Fecal Incontinence. References updated.
March 2021: Annual review. Minor edit to footnote on page 1. References updated.

April 2020: Annual review. Under Initial Treatment Assessment with PTNS, changed behavioral training requirement period from 6 months to 3 months. References updated.
April 2019: Annual review. Under Initial Treatment Assessment with PTNS, revised criteria under #2b from two antimuscarinics to two oral medications. Under Permanent Implantation of SNS section, under item #1 changed criteria from greater than 50% symptom relief to greater than or equal to.
April 2018: Annual review.
February 2017: Effective date

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