



Sacral Nerve Stimulation for Urinary Incontinence Clinical Coverage Criteria

Overview

Sacral nerve stimulation (SNS) is an implantable, permanent device that modulates the neural pathways controlling bladder function. This is one of several methods used to treat urinary urge incontinence, significant symptoms of urgency-frequency, or nonobstructive urinary retention, when other behavioral and/or pharmacologic therapies have failed.

Urge incontinence is the leakage of urine when there is a strong urge to void. Urgency-frequency is an uncontrollable urge to urinate resulting in very frequent, small volumes. Urinary retention is the inability to completely empty the bladder of urine.

Policy

This Policy applies to the following Fallon Health products:

- Commercial
- Medicare Advantage
- MassHealth ACO
- NaviCare
- PACE

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare has an NCD for Sacral Nerve Stimulation for Urinary Incontinence (230.18). National Government Services, Inc. does not have an LCD or LCA for sacral nerve stimulation for urinary incontinence. (MCD search 07-02-2021). Billing requirements for sacral nerve stimulation are addressed in Medicare Claims Processing Manual, Chapter 32, Section 40 – Sacral Nerve Stimulation.

For plan members enrolled in NaviCare and PACE plans, Fallon Health follows Medicare guidance for coverage determinations. In the event that there is no Medicare guidance or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health will follow guidance published by MassHealth. When there is no Medicare or MassHealth guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members. Each PACE plan member is assigned to an Interdisciplinary Team. When there is no Medicare or MassHealth guidance, the member's Interdisciplinary Team is responsible for coverage determinations.

Sacral nerve stimulation (SNS) requires Prior Authorization by Fallon Health. The below criteria must be met as supported by the treating provider(s) medical records.

Commercial and MassHealth members: Fallon Health covers sacral nerve stimulation (SNS) as treatment for urge incontinence, urgency-frequency, and non-obstructive urinary retention when ALL of the following criteria are met:

1. The plan member has not responded to prior behavioral and pharmacologic interventions over 6 months of treatment; and
2. Incontinence is not related to a neurologic condition; and
3. Symptoms of incontinence have been present for at least 12 months and have resulted in significant disability, such as the limited ability to work or participate in activities outside of the home; and
4. A test stimulation has demonstrated a 50% or greater improvement in incontinence, as documented in voiding diaries submitted for review with the request.

Behavioral interventions include pelvic floor exercises, timed voids and fluid management. Based on the reason for the incontinence, pharmacologic interventions can include 2 different anti-cholinergic drugs or a combination of an anti-cholinergic and a tricyclic anti-depressant or alpha blockers and cholinergics, with antibiotics used for urinary tract infections.

Medicare members: Fallon Health follows coverage criteria in Medicare NCD for Sacral Nerve Stimulation for Urinary Incontinence (230.18) for Medicare Advantage, NaviCare and PACE plan members.

NCD link: [Sacral Nerve Stimulation For Urinary Incontinence \(230.18\)](#)

Sacral nerve stimulation for urinary incontinence is covered for the treatment of urinary urge incontinence, urgency-frequency syndrome and urinary retention. Sacral nerve stimulation involves both a temporary test stimulation to determine if an implantable stimulator would be effective and a permanent implantation in appropriate candidates. Both the test and the permanent implantation are covered.

The following limitations for coverage apply to all indications:

- The plan member must be refractory to conventional therapy (documented behavioral, pharmacologic and/or surgical corrective therapy) and be an appropriate surgical candidate such that implantation with anesthesia can occur.
- Patients with stress incontinence, urinary obstruction, and specific neurologic diseases (e.g., diabetes with peripheral nerve involvement) that are associated with secondary manifestations of the above three indications are excluded.
- Patient must have had a successful test stimulation in order to support subsequent implantation. Before a patient is eligible for permanent implantation, he/she must demonstrate a 50% or greater improvement through test stimulation. Improvement is measured through voiding diaries.
- Patient must be able to demonstrate adequate ability to record voiding diary data such that clinical results of the implant procedure can be properly evaluated.

Exclusions

- Any use of SNS that does not meet the above criteria.
- Any other applications for SNS have not been proven in the peer-reviewed literature and are considered investigational. These non-covered uses include but may not be limited to: Stress incontinence or urge incontinence due to a neurologic condition, such as
 - Neurogenic detrusor overactivity,
 - Multiple sclerosis,
 - Spinal cord injury, and
 - Other types of chronic voiding dysfunction.
- Implantable neurostimulator pulse generator HCPCS L8679, Implantable neurostimulator radiofrequency receiver L8682, Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver L8683, Implantable neurostimulator pulse generator,

single array, L8685, Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension rechargeable, includes extension L8687, and External recharging system for implanted neurostimulator, replacement only. Are considered experimental/investigational and as such must meet coverage criteria under Fallon Heath's Experimental and Investigation Clinical Coverage Criteria.

Coding

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

Providers reimbursed according to the Medicare hospital outpatient prospective payment system (OPPS) methodology should use C codes to report drugs and devices.

Code	Description
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64581	Incision for implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)
64585	Revision or removal of peripheral neurostimulator electrode array
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
A4290	Sacral nerve stimulation test lead, each
C1767	Generator, neurostimulator (implantable) non-rechargeable
C1778	Lead, neurostimulator (implantable)

References

- Centers for Medicare & Medicaid Services. National Coverage Determination 230.18. Sacral Nerve Stimulation for Urinary Incontinence. Effective: January 1, 2002.
- Schmidt RA, et al. Sacral nerve stimulation for the treatment of refractory urinary urge incontinence. *J Urol.* 1999;162(2):352-357.
- Shaker HS, Hassouna M. Sacral nerve root neuromodulation: An effective treatment for refractory urge incontinence. *J Urol.* 1998;159:1516-1519.
- Altomare DF, Giannini I, Giuratrabocchetta S, Digennaro R. The effects of sacral nerve stimulation on continence are temporarily maintained after turning the stimulator off. *Colorectal Dis.* 2013 Dec;15(12):e741-8.
- Andretta E, Simeone C, Ostardo E, et al. Usefulness of sacral nerve modulation in a series of multiple sclerosis patients with bladder dysfunction. *J Neurol Sci.* 2014 Dec 15;347(1-2):257-61.
- Tsai PY, Wang CP, Hsieh CY, et al. Long-term sacral magnetic stimulation for refractory stress urinary incontinence. *Arch Phys Med Rehabil.* 2014 Dec;95(12):2231-8.
- Matzel KE, Chartier-Kastler E, Knowles CH, et. al. Sacral Neuromodulation: Standardized Electrode Placement Technique. *Neuromodulation.* 2017 Dec;20(8):816-824.
- Ammirati E, Giammò A, Manassero A, Carone R. Neuromodulation in urology, state of the art. *Urologia.* 2019 Aug 1:391560319866075.

Policy history

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 Approval(s): Utilization Management Committee: 06/2003
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references)

07/10/2021 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.