Sacral Nerve Stimulation for Urinary Incontinence Clinical Coverage Criteria

Overview

Sacral nerve stimulation, also known as sacral neuromodulation, is a minimally invasive therapeutic technique that involves electrical stimulation to a sacral nerve root with the goal of treating refractory urinary incontinence.

Policy

This Policy applies to the following Fallon Health products:
☒ Fallon Medicare Plus, Fallon Medicare Plus Central (Medicare Advantage)
☒ MassHealth ACO
☒ NaviCare HMO SNP (Dual Eligible Medicare Advantage and MassHealth)
☒ NaviCare SCO (MassHealth-only)
☒ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
☒ Community Care (Commercial/Exchange)

Sacral nerve stimulation for urinary incontinence requires prior authorization.

Medicare Advantage
Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Medicare statutes and regulations do not have coverage criteria for sacral nerve stimulation for urinary incontinence. Medicare has an NCD for Sacral Nerve Stimulation for Urinary Incontinence (230.18). Version Number 1. Effective Date of this Version 01/01/2002. National Government Services, Inc., the Part A and B Medicare Administrative Contractor (MAC) with jurisdiction over the Plan's service area does not have an LCD sacral nerve stimulation for urinary incontinence (Medicare Coverage Database search 07/22/2024).

Coverage criteria for sacral nerve stimulation for urinary incontinence are fully established by Medicare, therefore the Plan's coverage criteria are not applicable.

Link: **NCD Sacral Nerve Stimulation for Urinary Incontinence (230.18)**, Version Number 1, Effective Date of this Version 01/01/2002.

Indications and Limitations of Coverage

Effective January 1, 2002, sacral nerve stimulation 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 three indications:

- Patient 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) which 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.

Note: Medicare requires a successful trial of a sacral nerve stimulator prior to permanent implantation.

Removal only (without replacement) of a sacral nerve stimulator is considered medically necessary when the removal is required in order to treat a medical condition or complication, even if placement of the device did not meet Medicare coverage criteria.

However, revision or replacement of a sacral nerve stimulator that doesn't meet Medicare coverage criteria is non-covered and any revision or replacement to allow for the continued use of the non-covered device is not covered.

Billing requirements for sacral nerve stimulation are available in the Medicare Claims Processing Manual, Chapter 32, Section 40 – Sacral Nerve Stimulation,

MassHealth ACO
Fallon Health follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

MassHealth does not have Guidelines for Medical Necessity Determination for sacral nerve stimulation for urinary incontinence (MassHealth website search 07/22/2024), therefore, the Plan's coverage criteria are applicable.

NaviCare HMO SNP, NaviCare SCO
For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the

interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Fallon Health Clinical Coverage Criteria

Fallon Health Clinical Coverage Criteria apply to MassHealth ACO and Community Care members. For Medicare Advantage, NaviCare and PACE members, follow criteria described in the Policy section above.

Fallon Health considers sacral nerve stimulation medically necessary for the 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 documented 50% or greater improvement in incontinence, in daytime and nighttime incontinence episodes.

Test stimulation is considered medically necessary for members who meet criteria 1, 2 and 3 above.

Behavioral interventions include pelvic floor exercises, timed voids and fluid management. Based on the reason for the incontinence, pharmacologic interventions can include 2 different anticholinergic 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.

Exclusions

- Any use of sacral nerve stimulation that does not meet the above criteria.
- Any other applications for sacral nerve stimulation 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.

Coding

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

In 2022, the description of CPT code 64581 was revised to *Open implantation of neurostimulator electrode array, sacral nerve (transforaminal placement)* to clarify that it involves surgical exposure of the sacrum, previously required to suture permanent sacral leads in place. In revising the code definition from "incision" to “open,” the AMA is now requiring direct visualization of the surgical field to assign 64581. This was the implant approach for permanent sacral nerve stimulation in the past. However, the tined lead introduced in 2002 provided a less invasive approach with fluoroscopic guidance. This coding revision reflects the surgical approach. The effect of the definition change is that reporting codes 64561 and 64581 will be directed *by the surgical approach* for lead placement, *not by the stage* of lead placement (temporary or permanent) and *not by the type* of lead being placed (untined or tined) (Society of Urodynamics,

Female Pelvic Medicine & Urogenital Reconstruction. Important CPT Coding Update. December 6, 2021. Available at: https://sufuorg.com/news/important-cpt-coding-update.aspx).

The correct code to report for electrode array placement is based upon on the surgical technique used, not the type of lead placed (temporary or permanent), nor whether the array is tined or untined.

For electrode array placement (or replacement), use CPT code 64561 or 64581.

Report 64561 for percutaneous placement of an electrode array into a sacral foramen. The CPT codebook specifically states that this code "may be used to report either the temporary or permanent placement of percutaneous electrode arrays" if a percutaneous approach is used. Fluoroscopy and other imaging modalities to help guide placement are included and not separately reportable. If performed bilaterally, append Modifier 50. This code has a 10-day global period. Removal of temporary leads should not be reported whether performed within the global period or not. Test stimulation (CPT code 95970) is included in the placement code so would not be separately reported (American Urological Association. Coding for Sacral Nerve Stimulation Procedures. October 25, 2023. Available at: https://auanews.net/issues/articles/2023/october-extra-2023/coding-tips-and-tricks-coding-for-sacral-nerve-stimulation-procedures).

CPT code 64581 may be reported in place of CPT code 64561 (only) if the placement is performed in an open cutdown approach using a midline incision, exposure of the sacrum and direct placement of the array into the sacral foramen.

CPT code 64585 should not be reported for the removal of temporary leads, even outside of the global period.

For pulse generator placement (or replacement), use CPT code 64590.

Full system implantation (electrode array and generator/receiver), during the same operative session is reported with CPT code 64561 and CPT code 64590 (and 95972 if programming by surgeon), CPT code 64581 may be reported in place of CPT code 64561 (only) if the placement is performed in an open cutdown approach using a midline incision, exposure of the sacrum and direct placement of the array into the sacral foramen.

Test stimulation to confirm correct target site placement of the electrode array(s) and/or to confirm the functional status of the system is inherent to placement and is not separately reported as electronic analysis or programming of the neurostimulator system so should not be reported with implantation codes (e.g, CPT 64561, 64581, 64590, or 64595) or with electronic analysis with programming (CPT codes 95971 or 95972).

When an existing lead is removed and replaced by a new lead, only the lead implantation code 64561 may be assigned. For lead replacement, NCCI edits do not allow removal of the existing lead to be coded separately with implantation of the new lead.

When an existing generator is removed and replaced by a new generator, only the generator replacement code 64590 may be assigned. NCCI edits do not allow removal of the existing generator to be coded separately. Also note that, according to NCCI policy, use of the CPT code for generator "insertion or replacement" requires placement of a new generator. When the same generator is removed and then re-inserted, the "revision" code is used.

Per NCCI, Chapter 8, C. Nervous System, CPT code 64561 (Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed) is priced to include a percutaneous neuro test stimulation kit. This kit includes a test stimulation lead. HCPCS code A4290 (Sacral nerve stimulation test lead, each) should not be reported with CPT code 64561.

Code	Description
Test stimulation	
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64581	Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
Permanent lead implantation	
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64581	Open implantation of neurostimulator electrodes array; sacral nerve (transforaminal placement)
Generator placement or replacement	
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
Revision or removal of lead or generator	
64585	Revision or removal of peripheral neurostimulator electrode array
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
Analysis and programming	
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
95971	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95972	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional

Device C-codes

Providers reimbursed according to the Medicare hospital outpatient prospective payment system (OPPS) methodology are required to use C-codes to report devices.

Device	Code	Description
Test lead	C1897	Lead, neurostimulator test kit (implantable)
Lead	C1778	Lead, neurostimulator (implantable)
Generator (rechargeable)	C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
Generator	C1767	Generator, neurostimulator (implantable), non-rechargeable

(non-rechargeable)		
Patient programmer	C1787	Patient programmer, neurostimulator
Extension	C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)

Device A and L-codes

Device	Code	Description
Test lead	A4290	Sacral nerve stimulation test lead, each
Lead	L8680	Implantable neurostimulator electrode, each
Generator	L8679	Implantable neurostimulator pulse generator, any type
	L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
	L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
Patient programmer	L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
External recharger	L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only

References

1. Centers for Medicare & Medicaid Services. National Coverage Determination 230.18. Sacral Nerve Stimulation for Urinary Incontinence. Effective: January 1, 2002. Available at: https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=249.
2. Schmidt RA, et al. Sacral nerve stimulation for the treatment of refractory urinary urge incontinence. J Urol. 1999;162(2);352-357.
3. Shaker HS, Hassouna M. Sacral nerve root neuromodulation: An effective treatment for refractory urge incontinence. J Urol. 1998;159:1516-1519.
4. 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.
5. 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.
6. 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.
7. Matzel KE, Chartier-Kastler E, Knowles CH, et. al. Sacral Neuromodulation: Standardized Electrode Placement Technique. Neuromodulation. 2017 Dec;20(8):816-824.
8. Ammirati E, Giammò A, Manassero A, Carone R. Neuromodulation in urology, state of the art. Urologia. 2019 Aug 1:391560319866075.
9. Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction. Important CPT Coding Update. December 6, 2021. Available at: https://sufuorg.com/news/important-cpt-coding-update.aspx.
10. American Urological Association. Coding for Sacral Nerve Stimulation Procedures. October 25, 2023. Available at: https://auanews.net/issues/articles/2023/october-extra-2023/coding-tips-and-tricks-coding-for-sacral-nerve-stimulation-procedures.
11. Medtronic. Sacral Nerve Stimulation 2024 Coding and Payment Guide. Available at: https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/urology/sacral-neuromodulation/resources-support/reimbursement-coding.html.
12. Axonics. 2024 Reimbursement Guide. Axonics System for Sacral Neuromodulation. Available at: https://www.axonics.com/images/files/01-12-2024/105-0078-005rB_2024_SNM_Reimbursement_Guide.pdf.

Policy history

Origination date:	12/22/2003
Approval(s):	Utilization Management Committee: 06/2003 Technology Assessment Committee: 07/2000, 11/21/2003, 11/15/2012, 09/24/2014 (updated coding to reflect current codes, updated references) 09/23/2015 (updated references) 09/15/2016 (updated references), 09/26/2017 (updated references), 08/22/2018 (updated references), 09/10/2019 (updated references), 07/10/2021 (added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section), 07/23/2024 (annual review, updated Medicare Advantage and MassHealth ACO language in Policy section, clarified that test stimulation is considered medically necessary for members who meet criteria 1, 2 and 3, updated Coding section, updated References).

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.