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Medicare Advantage Policy Manual **Policy ID:** M-SUR134

Sacral Nerve Stimulation (Neuromodulation) for Pelvic Floor Dysfunction

Published:03/01/2025

Next Review: 12/2025

Last Review: 01/2025 ***Medicare Link(s) Revised:*** *03/01/2025*

IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

Sacral nerve neuromodulation (SNM), previously known as sacral nerve stimulation, is the implantation of a permanent device that modulates the neural pathways controlling bladder or rectal function. The SNM device consists of:

- An implantable pulse generator that delivers controlled electrical impulses;
- Wire leads that connect to the sacral nerves, most commonly the S3 nerve root;
- Two external components of the system help control the electrical stimulation;
- A control magnet is kept by the patient and can be used to turn the device on or off, and a console programmer is kept by the physician, used to adjust the settings of the pulse generator.

MEDICARE ADVANTAGE POLICY CRITERIA

Note: Medicare criteria requires a successful trial use of a stimulator prior to permanent

	implementation. If the request under review is for **trial** placement (test stimulator), the Medicare references will be applied as indicated, but criteria specific to trial outcomes will be bypassed. If the request under review is for **permanent** placement, Medicare references will be applied, including the criteria specific to trial requirements.
CMS Coverage Manuals*	For ***removal of the sacral nerve stimulation devices only,*** as well as ***revision/replacement*** of *not medically necessary devices*: Medicare Benefit Policy Manual Chapter 16 - General Exclusions From Coverage *See Section 180 in the following link:* §180 - Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare Note: Please read the applicable section, in its entirety, for complete criteria details. ***Removal only*** (without replacement) of a device may be allowed as medically necessary when the removal is required in order to treat a medical condition or complication. Even if initial permanent placement of the device did not meet medical necessity coverage criteria and the complication or subsequent medical condition is the result of a prior non-covered service, coverage may be allowed in select circumstances for the removal of the device. However, a procedure or device that doesn't meet medical necessity criteria is non-covered and any ***revision or replacement*** to allow for the *continued* use of the non-covered device would not meet Medicare's general requirements for coverage. For ***revision/replacement*** requests of previously placed *medically necessary devices*: Medicare Benefit Policy Manual Chapter 15 – Covered Medical and Other Health Services *See Section 120 in the following link:* §120 - Prosthetic Devices, D. Supplies, Repairs, Adjustments, and Replacement[1] Note: Replacement of previously placed medically necessary devices or their components that are non-functioning and irreparable (e.g., device malfunction, etc.) may be considered medically necessary in accordance

	with the above Medicare reference if the stimulator continues to be medically indicated and is no longer under manufacturer warranty or if the component is not included under the warranty.[1]
National Coverage Determinations (NCDs)*	For the initial placement of a sacral nerve device for treatment of ***urinary urge incontinence, urgency-frequency syndrome, urinary retention, stress incontinence, urinary obstruction, as well as specific neurologic diseases associated with secondary manifestations of the covered indications***: ✓ Sacral Nerve Stimulation For Urinary Incontinence (230.18)
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles *	For the initial placement of a sacral nerve device for treatment of ***fecal incontinence, chronic constipation, or chronic pelvic pain***: ✓ Sacral Nerve Stimulation for Urinary and Fecal Incontinence R3 (A53017) **Scroll to the "Public Version(s)" section at the bottom of the Article for links to prior versions if necessary.

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

For initial placement:

- History and Physical documenting symptoms (frequency and duration), cause(s), and conditions/indications being treated, as well as failed or inability to tolerate conventional therapy;
- Documentation supporting appropriateness of surgical candidacy and tolerance of anesthesia;
- Name of specific FDA approved device/system used.
- Specify whether the request is for a trial (test) stimulation or permanent implantation.
    - For permanent placement, documentation of trial results is required.

For replacement:

- For replacement of irreparable devices or their components, documentation must support reason for replacement (e.g., device malfunction, etc.) and whether or not the stimulator is still under manufacturer warranty or that the component excluded from the warranty.

For revisions and removal only (without replacement):

- Revisions to previously placed medically necessary devices and removals do not require additional documentation.

REGULATORY STATUS

Axonics Sacral Neuromodulation System

- In 2019, The Axonics Sacral Neuromodulation System received FDA approval for the treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments.
- In 2019, The Axonics Sacral Neuromodulation System received FDA approval for the treatment of urinary retention and the symptoms of overactive bladder, including urge incontinence and significant symptoms of urgency-frequency alone or in combination, in patients who have failed or could not tolerate more conservative treatments.
- Axonics SNM Therapy is contraindicated for patients who have not demonstrated an appropriate response to test stimulation; or patients who are unable to operate the Axonics SNM Systems.
- Medtronic Interstim® Sacral Nerve Stimulation™ systemIn 1997, the Medtronic Interstim® Sacral Nerve Stimulation™ system received U.S. Food and Drug Administration (FDA) approval for marketing for the indication of urinary urge incontinence in patients who have failed or could not tolerate more conservative treatments.
- In 1999 the device received FDA approval for the additional indications of urgency-frequency and urinary retention in patients without mechanical obstruction.
- In 2006, the Medtronic Interstim® II System received FDA approval for treatment of intractable cases of overactive bladder and urinary retention. The new device is smaller and lighter than the original system and is reported to be suited for those with lower energy requirements or small stature. The device also includes updated software and programming options.
- In 2011, the Medtronic InterStim System received FDA approval for the indication of chronic fecal incontinence in patients who have failed or could not tolerate more conservative treatments.
- In 2020, the Medtronic InterStim™ Micro system received FDA approval for above indications. This small device has a rechargeable battery designed to last **15 years.** Recharging can be done 1x per week.
- In 2022, the Medtronic InterStimX™ system received FDA approval for the above indications. This device does not require recharging and has a 15 year battery life when using low energy settings. **Note:** The above SNM devices have not been specifically approved by FDA for treatment of chronic pelvic pain.
- In 2023, the Virtis™ Sacral Neuromodulation System (Nuvectra) was approved by the FDA for treatment of urinary retention and symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency in patients who have failed more conservative treatments.

Note: The fact a new service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. The FDA determines safety and effectiveness of a device or drug but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, CMS or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

CROSS REFERENCES

Electrical Stimulation and Electromagnetic Therapy Devices, Durable Medical Equipment, Policy No. M-83

Periurethral Transperineal Adjustable Balloon Continence Device, Medicine, Policy No. M-176

Posterior Nerve Stimulation for Voiding Dysfunction, Surgery, Policy No. M-154

Peripheral Nerve Stimulation (PNS) and Peripheral Nerve Field Stimulation (PNFS), Surgery, Policy No. M-205

REFERENCES

1. Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §40.4 - Items Covered Under Warranty

CODING

NOTE: HCPCS code C1823 is NOT the correct code to use for reporting these services. Please refer to the codes listed below for guidance.

Codes	Number	Description
CPT	0786T	Insertion or replacement of percutaneous electrode array, sacral, with integrated neurostimulator, including imaging guidance, when performed
	0787T	Revision or removal of neurostimulator electrode array, sacral, with integrated neurostimulator
	0788T	Electronic analysis with simple programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, spinal cord or sacral nerve, 1-3 parameters
	0789T	Electronic analysis with complex programming of implanted integrated neurostimulation system (eg, electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, spinal cord or sacral nerve, 4 or more parameters
	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)
	64585	Revision or removal of peripheral neurostimulator electrode array
	64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
	64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array
	64596	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; initial electrode array
	64597	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; each additional electrode array (List separately in addition to code for primary procedure)
	64598	Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator
	95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., 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	; with simple spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
	95972	; with complex spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
HCPCS	C1767	Generator, neurostimulator (implantable), non-rechargeable
	C1778	Lead, neurostimulator (implantable)
	C1883	Adapter/extension, pacing lead or neurostimulator lead (implantable)
	L8678	Electrical stimulator supplies (external) for use with implantable neurostimulator, per month
	L8679	Implantable neurostimulator, pulse generator, any type
	L8680	Implantable neurostimulator electrode, each *(Code non-covered by Medicare – see L8679)*
	L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
	L8682	Implantable neurostimulator radiofrequency receiver
	L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
	L8684	Radiofrequency transmitter (external) for use with implantable sacral root

	L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension *(Code non-covered by Medicare – see L8679)*
	L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension *(Code non-covered by Medicare – see L8679)*
	L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension *(Code non-covered by Medicare – see L8679)*
	L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension *(Code non-covered by Medicare – see L8679)*
	L8689	External recharging system for battery (internal) for use with implantable neurostimulator

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*