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

Sacral Nerve Modulation/Stimulation for Pelvic Floor Dysfunction

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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

CMS Coverage Manuals* None

National Coverage Determinations (NCDs)*	For the 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 (LCAs)*	For the 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 LCA 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:

- 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;
- Documentation of successful test stimulation to support subsequent stimulation.

REGULATORY STATUS

- In 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.
- The Interstim device has not been specifically approved by FDA for treatment of chronic pelvic pain.

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." *(Noridian LCD L35008)* 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

Transanal Radiofrequency Treatment of Fecal Incontinence, Surgery, Policy No. M-129

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

None

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	64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
	64581	Incision for implantation of neurostimulator electrode array; 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

	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
	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