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Medicare Advantage Policy Manual **Policy ID:** M-SUR205

Peripheral Nerve Stimulation (PNS) and Peripheral Nerve Field Stimulation (PNFS)

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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

Peripheral nerve stimulation (PNS) is the placement of a lead by a physician (via open surgical or percutaneous approach) near the known anatomic location of a peripheral nerve. PNS, like deep brain stimulation and spinal cord stimulation modulates the nervous system with electrical stimulation to lessen chronic pain and other conditions.

Peripheral nerve field stimulation (PNFS) is the stimulation of the subcutaneous distal distribution of an area of pain (indirectly stimulating the peripheral nerve). In both PNS and PNFS leads are composed of multiple contacts (of varying number) connected to an external pulse generator when temporary and implanted when made permanent. Other types of electrical nerve stimulation include, but are not be limited to, the following:

- Transcutaneous electrical nerve stimulation (TENS) delivers impulses below the skin, to alleviate pain.
- Percutaneous electrical nerve stimulation (PENS) is similar to TENS, except PENS requires electrodes to be inserted into the skin.
- Percutaneous neuromodulation therapy (PNT) is similar to PENS. PNT is an electrical stimulation therapy in which *10 fine filament electrodes* are temporarily placed in the deep tissues *near the area causing pain* (with or without radiating lower extremity pain).

MEDICARE ADVANTAGE POLICY CRITERIA

Note:

- Example of an *implantable* peripheral nerve stimulator for chronic pain include the StimRouter and SPRINT® systems.
- Please refer to the Deep Brain Stimulation, Occipital Nerve Stimulation, Sacral Nerve Stimulation, Percutaneous Neuromodulation Therapy (PNT), and other electrical stimulation device policies for specific neuromodulation or stimulation therapies related to pain.
- Additional stimulation services for pain may be reviewed by an external vendor (e.g., spinal cord stimulators).
- Finally, other nerve stimulation services are outside the scope of this Medicare Advantage medical policy (e.g., TENS and PENS) and may be considered medically necessary.

CMS Coverage Manuals*	For ***removal of the PNS 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 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)*	Electrical Nerve Stimulators (160.7) Review Section A. Implantable Peripheral Nerve Stimulators.
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles*	***Peripheral Nerve Stimulation*** — LCD L37360 Billing and coding guidelines for ***Peripheral Nerve Stimulation*** — Article A55531 **Scroll to the "Public Version(s)" section at the bottom of the LCD 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:

- Description of the planned treatment, including the indication being treated, symptoms, prior attempted therapies, and the type of electrical stimulation;
- Name of stimulation device.

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.
- Name of stimulation device.

For revisions and removal only (without replacement):

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

REGULATORY STATUS

The Bioness® StimRouter™ received its initial U.S. Food and Drug Administration (FDA) 510K approval in February 2015. In March of 2016, the StimQ Peripheral Nerve Stimulator (PNS) System received FDA 510(k) approval and in July 2018, the SPRINT® Peripheral Nerve Stimulation System (SPR Therapeutics, Inc) was cleared for marketing by the FDA.

Note, none of these systems are intended to treat pain in the craniofacial region.

Of note, the fact a service or procedure has been FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. Medicare contractors evaluate services, procedures, drugs or technology to determine if they may be considered Medicare covered services. 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

Percutaneous Neuromodulation Therapy (PNT), Surgery, Policy No. M-44

Sacral Nerve Stimulation (Neuromodulation) for Pelvic Floor Dysfunction, Surgery, Policy No. M-134

Posterior Tibial Nerve Stimulation (PTNS), Surgery, Policy No. M-154

Occipital Nerve Stimulation (ONS), Surgery, Policy No. M-174

REFERENCES

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

2. StimRouter Neuromodulation System. [cited 01/23/2024]; Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf14/K142432.pdf
3. Federal Register Vol. 81, No. 151, August 5, 2016, Bioness StimRouter Category B IDE. [cited 01/23/2024] Available from: https://www.gpo.gov/fdsys/pkg/FR-2016-08-05/pdf/2016-18546.pdf

CODING

Codes	Number	Description
CPT	64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
	64575	Incision for implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
	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
	64999	Unlisted procedure, nervous system
	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 neuromodulation, 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
	97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)
	97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes

Codes	Number	Description
HCPCS	C1778	Lead, neurostimulator (implantable)
	L8679	Implantable neurostimulator, pulse generator, any type
	L8680	Implantable neurostimulator electrode, each
	L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver

***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.*