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Medicare Advantage Policy Manual **Policy ID:** M-SUR216

Responsive Neurostimulation

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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

Standard therapy for seizures, including focal seizures, includes treatment with one or more of various antiepileptic drugs (AEDs), surgical techniques (resection of the seizure focus, or epilepsy surgery), and electrical stimulation. Responsive neurostimulation (RNS) provides cortical stimulation in response to detection of specific seizure-related electrical signals. RNS shares some features with deep brain stimulation (DBS) but is differentiated by its use of direct cortical stimulation and by its use in both monitoring and stimulation. The RNS system provides stimulation in response to detection of specific epileptiform patterns, while DBS provides continuous or intermittent stimulation at preprogrammed settings.

MEDICARE ADVANTAGE POLICY CRITERIA

Note: This policy only applies to ***responsive neurostimulation*** (RNS). For ***deep brain stimulation*** (DBS) or ***vagus nerve stimulation*** (VNS), see *Cross References* below.

CMS Coverage Manuals*	For ***removal only of an RNS device,*** as well as ***revision or replacement*** of *not medically necessary devices*: Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage ***See Section 180****:* §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 be expected to 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****:* §120 - Prosthetic Devices, D. Supplies, Repairs, Adjustments, and Replacement 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)*	None Deep brain stimulation (DBS) and RNS or cortical stimulation are different types of neurostimulation procedures. Therefore, the Medicare NCD for DBS does not apply to RNS treatment of seizures or epilepsy.
Noridian Healthcare Solutions (Noridian) Local	None

Coverage Determinations (LCDs) and Articles*	
Medical Policy Manual	*Medicare coverage guidance is not available for responsive neurostimulation (RNS) or responsive cortical stimulation. Therefore, the health plan's medical policy is applicable.* For the ***initial placement*** of RNS device: Responsive Neurostimulation, Surgery, Policy No. 216 *(see "NOTE" below)*

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (*Medicare IOM Pub. No. 100-04, Ch. 23, §30 A*). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an ***objective, evidence-based process, based on authoritative evidence***. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

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 exam, including requirements as outlined by the policy criteria
- Number of seizure foci
- Documentation of seizure occurrence over the prior 3 months
- Clinical documentation demonstrating medicine-refractory symptoms
- Clinical documentation demonstrating that the patient is not a candidate for focal resective epilepsy surgery
- Presence of other conditions, such as a neurological disorder

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.

For revisions and removal only (without replacement):

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

REGULATORY STATUS

In November 2013, the NeuroPace RNS® System (NeuroPace) was approved by FDA through the premarket approval process for the following indication[2]:

"The RNS® System is an adjunctive therapy in reducing the frequency of seizures in individuals 18 years of age or older with partial onset seizures who have undergone diagnostic testing that localized no more than 2 epileptogenic foci, are refractory to two or more antiepileptic medications, and currently have frequent and disabling seizures (motor partial seizures, complex partial seizures and/ or secondarily generalized seizures). The RNS® System has demonstrated safety and effectiveness in patients who average 3 or more disabling seizures per month over the three most recent months (with no month with fewer than two seizures), and has not been evaluated in patients with less frequent seizures."

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 necessarily 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, Medicare 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

Investigational (Experimental) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services, Medicine, Policy No. M-149

Vagus Nerve Stimulation (VNS), Surgery, Policy No. M-74

Deep Brain Stimulation (DBS), Surgery, Policy No. 84

REFERENCES

1. Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §40.4 - Items Covered Under Warranty
2. Food and Drug Administration. Summary of Safety and Effectiveness Data: RNS System 2013. [cited 1/2/2024]; Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100026b.pdf

CODING

Codes	Number	Description
CPT	61850	Twist drill or burr hole(s) for implantation of neurostimulator electrodes, cortical
	61860	Craniectomy or craniotomy for implantation of neurostimulator electrodes, cerebral, cortical
	61863	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; first array
	61864	; each additional array (List separately in addition to primary procedure)
	61880	Revision or removal of intracranial neurostimulator electrodes

	61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
	61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays
	61888	Revision or removal of cranial neurostimulator pulse generator or receiver
	61889	Insertion of skull-mounted cranial neurostimulator pulse generator or receiver, including craniectomy or craniotomy, when performed, with direct or inductive coupling, with connection to depth and/or cortical strip electrode array(s)
	61891	Revision or replacement of skull-mounted cranial neurostimulator pulse generator or receiver with connection to depth and/or cortical strip electrode array(s)
	61892	Removal of skull-mounted cranial neurostimulator pulse generator or receiver with cranioplasty, when performed
	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	; with simple spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
HCPCS	L8678	Electrical stimulator supplies (external) for use with implantable neurostimulator, per month
	L8679	Implantable neurostimulator, pulse generator, any type
	L8680	Implantable neurostimulator electrode, each
	L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, 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)*

***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.*