BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Responsive Neurostimulation for the Treatment of Refractory Focal Epilepsy

Policy #: 574
Latest Review Date: April 2025
Category: Surgery

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **responsive neurostimulation** (e.g., NeuroPace RNS System) as a **covered benefit** for patients with focal epilepsy who meet **ALL** of the following criteria:

- Are 18 years or older.
- Have a diagnosis of focal seizures with one or two well-localized seizure foci identified.
- Have an average of three or more disabling seizures (e.g., motor focal seizures, complex focal seizures, or secondary generalized seizures) per month over the prior three months;
- Are refractory to medical therapy (have failed two or more appropriate antiepileptic medications at therapeutic doses).
- Are not candidates for focal resective epilepsy surgery (e.g., have an epileptic focus near eloquent cerebral cortex; have bilateral temporal epilepsy).
- Do not have contraindications for RNS placement. *

Blue Advantage will treat **responsive neurostimulation** as a **non-covered benefit** and as **investigational** for all other indications.

Policy Guidelines:

*Contraindications for RNS placement include more than three specific seizure foci, the presence of primary generalized epilepsy or the presence of a rapidly progressive neurologic disorder.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contracts and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Responsive neurostimulation (RNS) for the treatment of epilepsy involves the use of one or more implantable electric leads that serve as both a seizure detection and neurostimulation function. The device is programmed using a proprietary algorithm to recognize seizure patterns from electrocorticography output and to deliver electrical stimulation with the goal of terminating a seizure. One device, the NeuroPace RNS System, has U.S. Food and Drug Administration (FDA) approval for the treatment of refractory focal (formerly partial) epilepsy.

Epilepsy Treatment

Medical Therapy for Focal Seizures

Focal seizures (previously referred to as partial seizures) arise from a discrete area of the brain and can cause a range of symptoms, depending on the seizure type and the brain area involved.

Standard therapy for seizures, including focal seizures, includes treatment with one or more of various antiepileptic drugs (AEDs) which include newer AEDs, such as oxcarbazepine, lamotrigine, topiramate, gabapentin, pregabalin, levetiracetam, tiagabine, and zonisamide. Currently, response to AEDs is less than ideal: one systematic review of comparing newer AEDs for refractory focal epilepsy reported an overall average responder rate in the treatment groups of 34.8%. As a result, a substantial number of individuals do not achieve good seizure control with medications alone.

Surgical Therapy for Seizures

When a discrete seizure focus can be identified, seizure control may be achieved through resection of the seizure focus (epilepsy surgery). For temporal lobe epilepsy, an RCT has demonstrated that surgery for epilepsy was superior to prolonged medical therapy in reducing seizures associated with impaired awareness and in improving quality of life. Surgery for refractory focal epilepsy (excluding simple focal seizures) is associated with a five-year freedom from seizures of 52%, with 28% of seizure-free individuals able to discontinue AEDs. Selection of appropriate individuals for epilepsy surgery is important because those with nonlesional extratemporal lobe epilepsy have worse outcomes after surgery than those with nonlesional temporal lobe epilepsy. Some individuals are not candidates for epilepsy surgery if the seizure focus is located in an eloquent area of the brain or other region that cannot be removed without risk of significant neurological deficit.

Neurostimulation for Neurologic Disorders

Electrical stimulation at one of several locations in the brain has been used as therapy for epilepsy, either as an adjunct to or as an alternative to medical or surgical therapy. Vagus nerve stimulation (VNS) has been widely used for refractory epilepsy, following FDA approval of a VNS device in 1997 and 2 RCTs evaluating VNS in epilepsy. Although the mechanism of action for VNS is not fully understood, VNS is thought to reduce seizure activity through the activation of vagal visceral afferents with diffuse central nervous system projections, leading to a widespread effect on neuronal excitability.

Stimulation of other locations in the neuroaxis has been studied for a variety of neurologic disorders. Electrical stimulation at deep brain nuclei (deep brain stimulation [DBS]) involves the use of chronic, continuous stimulation of a target. It has been most widely used in the treatment of Parkinson's disease and other movement disorders but has also been investigated for treating epilepsy. DBS of the anterior thalamic nuclei was studied in an RCT, the Stimulation of the Anterior Nucleus of the Thalamus for Epilepsy (SANTE) trial, but DBS is not currently approved by the FDA for stimulation of the anterior thalamic nucleus. Stimulation of the cerebellar and hippocampal regions and the subthalamic, caudate, and centromedian nuclei have also been evaluated for the treatment of epilepsy.

Responsive Neurostimulation for Epilepsy

RNS shares some features with 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 in pre-programmed settings.

Development of the RNS system arose observations related to the effects of cortical electrical stimulation for seizure localization. It has been observed that electrical cortical stimulation can terminate induced and spontaneous electrographic seizure activity in humans and animals. Individuals with epilepsy may undergo implantation of subdural monitoring electrodes for the purposes of seizure localization, which at times have been used for neurostimulation to identify eloquent brain regions. Epileptiform discharges that occur during stimulation for localization can be stopped by a train of neighboring brief electrical stimulations.

In tandem with the recognition that cortical stimulation can stop epileptiform discharges was the development of fast pre-ictal seizure prediction algorithms. These algorithms interpret electrocorticographic data from detection leads situated over the cortex. The RNS process thus includes electrocorticographic monitoring via cortical electrodes, analysis of data through a proprietary seizure detection algorithm, and delivery of electrical stimulation via both cortical and deep implanted electrodes in an attempt to halt a detected epileptiform discharge.

One system, the Neuropace RNS® System, is currently approved by the FDA and is commercially available. The system consists of an implantable neurostimulator, a cortical strip lead, implantable components and accessories, a tablet and telemetry wand, an individual data management system, a remote monitor for use by the individual to upload data to the data management system, and a magnet for individuals to withhold therapy or to activate electrocorticograhic storage. The responsive neurostimulation stimulator and implant monitor the brain's electrical activity and deliver electrical stimulation when warranted. Before device implantation, the individual undergoes seizure localization, which includes inpatient video-electroencephalographic monitoring and magnetic resonance imaging for the detection of epileptogenic lesions. Additional testing may include electroencephalography with intracranial electrodes, intraoperative or extraoperative stimulation with subdural electrodes, additional imaging studies, and/or neuropsychological testing, and intracarotid amytal testing (also referred to as Wada testing). The selection and location of the leads are based on the location of seizure foci. Cortical strip leads are recommended for seizure foci on the cortical surface, while the depth leads are recommended for seizure foci beneath the cortical surface. The implantable neurostimulator and cortical and/or depth leads are implanted intracranially. The neurostimulator is initially programmed in the operating room to detect electrocorticographic activity. Responsive therapy is initially set up using standard parameters from the electrodes from which electrical activity is detected. Over time, the responsive stimulation settings are adjusted on the basis of electrocorticography data, which are collected by the individual through interrogation of the device with the telemetry wand and transmitted to the data management system.

Responsive Neurostimulation for Seizure Monitoring

Although the intent of the electrocorticography component of the RNS system is to provide input as a trigger for neurostimulation, it also provides continuous seizure mapping data (chronic unlimited cortical electrocorticography [CURE]) that may be used by practitioners to evaluate individuals' seizures. In particular, the seizure mapping data have been used for surgical planning of individuals who do not experience adequate seizure reduction with RNS placement. Several studies have described the use of the RNS in evaluating seizure foci for epilepsy surgery or for identifying whether seizure foci are unilateral.

KEY POINTS:

The most recent literature review was updated through February 21, 2025.

Summary of Evidence

For individuals who have refractory focal epilepsy who receive responsive neurostimulation (RNS), the evidence includes an industry-sponsored randomized controlled trial (RCT), which was used for Food and Drug Administration approval of the NeuroPace® RNS System, as well as several published follow-up analyses. Relevant outcomes are symptoms, morbid events, quality of life, and treatment-related mortality and morbidity. The randomized controlled trial was well designed and well conducted; it reported that RNS is associated with improvements in mean seizure frequency in individuals with refractory focal epilepsy, with an absolute difference in change in seizure frequency of about 20% between groups; however, the percentage of treatment responders with at least a 50% reduction in seizures did not differ from sham control. Overall, the results suggested a modest reduction in seizure frequency in a subset of individuals. The number of adverse events reported in the available studies is low, although the data on adverse events were limited because of small study samples. Generally, individuals who are candidates for RNS are severely debilitated and have few other treatment options, so the benefits are likely high relative to the risks. Individuals who are not candidates for respective epilepsy surgery and have few treatment options may benefit from RNS. The evidence is sufficient to determine that technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

No relevant clinical practice guidelines were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

KEY WORDS:

RNS System, NeuroPace®, epilepsy, partial seizures, responsive neurostimulation, electrocorticography, chronic unlimited cortical electrocorticography, CURE, Responsive Cortical Stimulation

APPROVED BY GOVERNING BODIES:

In November 2013, the NeuroPace RNS® System (Neuropace) was approved by the FDA through the premarket approval process for the following indications:

"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 two epileptogenic foci, are refractory to 2 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 2 seizures), and has not been evaluated in patients with less frequent seizures."

BENEFIT APPLICATION:

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:

There are no specific CPT codes for the insertion of this device. It would be reported with the CPT codes for insertion of a neurostimulator such as the following:

CPT Codes:

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 (e.g., 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	; 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) (Effective 1/1/24)
61891	Revision or replacement of skull-mounted cranial neurostimulator pulse generator or receiver with connection to depth and/or cortical strip electrode array(s)(Effective 1/1/24)

61892	Skull-mounted cranial neurostimulator pulse generator or receiver removal (Effective 1/1/24)
95836	Electrocorticogram from an implanted brain neurostimulator pulse generator/transmitter, including recording, with interpretation and written report, up to 30 days
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

HCPCS Codes:

L8680	Implantable neurostimulator electrode, each
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

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POLICY HISTORY:

Adopted for Blue Advantage, November 2014
Available for comment December 2, 2014 through January 16, 2015
Medical Policy Group, April 2016
Medical Policy Group, April 2017
Medical Policy Group, April 2018
Medical Policy Group, December 2018: 2019 CPT coding update.
Medical Policy Group, May 2019
Medical Policy Group, October 2019
Medical Policy Group, May 2020
Medical Policy Group, May 2021
Medical Policy Group, April 2022
Medical Policy Group, May 2023
Medical Policy Group, November 2023: 2024 annual CPT coding update. Added 61889,61891, 61892.
UM Committee, December 2023: Policy approved by UM Committee for use for Blue Advantage business.
Medical Policy Group, May 2024
UM Committee, May 2024: Annual review of policy approved by UM Committee for use for Blue Advantage business.
Medical Policy Group, April 2025
