



# Louisiana

## Responsive Neurostimulation for the Treatment of Refractory Focal Epilepsy

**Policy #** 00674

**Original Effective Date:** 11/01/2019

**Current Effective Date:** 09/14/2020

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Note: Vagus Nerve Stimulation is addressed separately in medical policy 00134.*

*Note: Deep Brain Stimulation is addressed separately in medical policy 00024*

### When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider responsive neurostimulation for patients with focal epilepsy to be **eligible for coverage.\*\***

#### Patient Selection Criteria

Coverage eligibility will be considered for responsive neurostimulation for patients with focal epilepsy when ALL of the following criteria are met:

- Are 18 years or older AND
- Have a diagnosis of focal seizures with 1 or 2 well-localized seizure foci identified; AND
- Have an average of 3 or more disabling seizures (eg, motor focal seizures, complex focal seizures, or secondary generalized seizures) per month over the prior 3 months; AND
- Are refractory to medical therapy (have failed  $\geq 2$  appropriate antiepileptic medications at therapeutic doses); AND
- Are not candidates for focal resective epilepsy surgery (eg, have an epileptic focus near the eloquent cerebral cortex; have bilateral temporal epilepsy); AND
- Do not have contraindications for responsive neurostimulation device placement (see Policy Guidelines section).

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### **When Services Are Considered Investigational**

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers responsive neurostimulation for all other indications to be **investigational**.\*

The use of responsive neurostimulation when patient selection criteria are not met is considered to be **investigational**.\*

### **Policy Guidelines**

Contraindications for responsive neurostimulation device placement include 3 or more specific seizure foci, presence of primary generalized epilepsy, or presence of a rapidly progressive neurologic disorder.

### **Background/Overview**

#### **Epilepsy Treatment**

#### **Medical Therapy for Seizures**

Standard therapy for seizures, including focal seizures, includes treatment with one or more of various antiepileptic drugs, which include newer antiepileptic drugs, such as oxcarbazepine, lamotrigine, topiramate, gabapentin, pregabalin, levetiracetam, tiagabine, and zonisamide. Currently, response to antiepileptic drugs is less than ideal: one systematic review comparing newer antiepileptic drugs for refractory focal epilepsy reported an overall average responder rate in treatment groups of 34.8%. As a result, a substantial number of patients 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, a randomized controlled trial 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

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focal epilepsy (excluding simple focal seizures) is associated with 5-year freedom from seizure rates of 52%, with 28% of seizure-free individuals able to discontinue antiepileptic drugs. Selection of appropriate patients 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 patients 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 neurologic 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 has been widely used for refractory epilepsy, following U.S. Food and Drug Administration (FDA) approval of a vagus nerve stimulation device in 1997 and 2 randomized controlled trials evaluating vagus nerve stimulation in epilepsy. Although the mechanism of action for vagus nerve stimulation is not fully understood, vagus nerve stimulation is thought to reduce seizure activity through 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 of deep brain nuclei (deep brain stimulation) involves the use of chronic, continuous stimulation of a target. It has been most widely used in the treatment of Parkinson disease and other movement disorders, and has been investigated for treating epilepsy. Deep brain stimulation of the anterior thalamic nuclei was studied in a randomized control trial, the Stimulation of the Anterior Nucleus of the Thalamus for Epilepsy trial, but deep brain stimulation is not currently approved by 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**

Responsive neurostimulation shares some features with deep brain stimulation, but is differentiated by its use of direct cortical stimulation and by its use in both monitoring and stimulation. The responsive neurostimulation system provides stimulation in response to detection of specific epileptiform patterns, while deep brain stimulation provides continuous or intermittent stimulation at preprogrammed settings.

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Development of the responsive neurostimulation system arose from 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. Patients 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 development of fast pre-ictal seizure prediction algorithms. These algorithms interpret electrocorticographic data from detection leads situated over the cortex. The responsive neurostimulation 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 device, the NeuroPace RNS<sup>®</sup> System, is currently approved by FDA and is commercially available.

### **Responsive Neurostimulation for Seizure Monitoring**

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

This review does not further address use of responsive neurostimulation exclusively for seizure monitoring.

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### **FDA or Other Governmental Regulatory Approval**

#### **U.S. Food and Drug Administration (FDA)**

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

“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.”

FDA product code: PFN.

### **Rationale/Source**

Responsive neurostimulation for the treatment of epilepsy involves the use of one or more implantable electric leads that serve 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.

For individuals who have refractory focal epilepsy who receive responsive neurostimulation, the evidence includes an industry-sponsored randomized controlled trial, which was used for FDA approval of the NeuroPace RNS System, as well as case series. 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 responsive neurostimulation is associated with improvements in mean seizure frequency in patients with refractory focal epilepsy, with an absolute difference in change in seizure frequency of about 20% between groups, though 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 patients.

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The number of adverse events reported in the available studies is low, although the data on adverse events were limited because small study samples. Generally, patients who are candidates for responsive neurostimulation are severely debilitated and have few other treatment options, so the benefits are likely high relative to the risks. In particular, patients who are not candidates for resective epilepsy surgery and have few treatment options may benefit from responsive neurostimulation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Consensus input from clinical vetting recommended that responsive neurostimulation is medically necessary for a subgroup of patients with refractory focal epilepsy. Therefore, responsive neurostimulation may be considered medically necessary in patients with medication-refractory focal epilepsy who are not candidates for epilepsy surgery.

### **Supplemental Information**

#### **Clinical Input From Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 2 specialty medical societies (3 responses) and 5 academic medical centers (4 responses) when this policy was under development in 2014. There was consensus among reviewers that responsive neurostimulation is medically necessary for patients with focal epilepsy with 1 to 2 foci who are not candidates for resective epilepsy surgery.

#### **Practice Guidelines and Position Statements**

##### **American Academy of Neurology**

In 2013, guidelines on vagus nerve stimulation for the treatment of epilepsy were issued by the American Academy of Neurology. The guidelines made the following recommendations: “vagus nerve stimulation may be considered for seizures in children, for Lennox-Gastaut syndrome associated seizures, and for improving mood in adults with epilepsy (Level C). Vagus nerve stimulation may be considered to have improved efficacy over time (Level C). Children should be

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carefully monitored for site infection after vagus nerve stimulation implantation.” The Academy indicated that more information would be needed on the treatment of primary generalized epilepsy in adults (only 1 class II article addressed this population). The responsive neurostimulation system was not mentioned in these guidelines.

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**Medicare National Coverage**

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are shown in Table 1.

**Table 1. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT02403843 <sup>a</sup>	RNS® System Post-Approval Study in Epilepsy	375	May 2023

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

**References**

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, “Responsive Neurostimulation for the Treatment of Refractory Focal Epilepsy”, 7.01.143, May 2020.
2. Costa J, Fareleira F, Ascencao R, et al. Clinical comparability of the new antiepileptic drugs in refractory partial epilepsy: a systematic review and meta-analysis. *Epilepsia*. Jul 2011;52(7):1280-1291. PMID 21729036
3. Wiebe S, Blume WT, Girvin JP, et al. A randomized, controlled trial of surgery for temporal-lobe epilepsy. *N Engl J Med*. Aug 2 2001;345(5):311-318. PMID 11484687

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4. de Tisi J, Bell GS, Peacock JL, et al. The long-term outcome of adult epilepsy surgery, patterns of seizure remission, and relapse: a cohort study. *Lancet*. Oct 15 2011;378(9800):1388-1395. PMID 22000136
5. Noe K, Sulc V, Wong-Kisiel L, et al. Long-term outcomes after nonlesional extratemporal lobe epilepsy surgery. *JAMA Neurol*. Aug 2013;70(8):1003-1008. PMID 23732844
6. Fridley J, Thomas JG, Navarro JC, et al. Brain stimulation for the treatment of epilepsy. *Neurosurg Focus*. Mar 2012;32(3):E13. PMID 22380854
7. Fisher RS. Therapeutic devices for epilepsy. *Ann Neurol*. Feb 2012;71(2):157-168. PMID 22367987
8. Kossoff EH, Ritzl EK, Politsky JM, et al. Effect of an external responsive neurostimulator on seizures and electrographic discharges during subdural electrode monitoring. *Epilepsia*. Dec 2004;45(12):1560-1567. PMID 15571514
9. Anderson WS, Kossoff EH, Bergey GK, et al. Implantation of a responsive neurostimulator device in patients with refractory epilepsy. *Neurosurg Focus*. Sep 2008;25(3):E12. PMID 18759613
10. DiLorenzo DJ, Mangubat EZ, Rossi MA, et al. Chronic unlimited recording electrocorticography-guided resective epilepsy surgery: technology-enabled enhanced fidelity in seizure focus localization with improved surgical efficacy. *J Neurosurg*. Jun 2014;120(6):1402-1414. PMID 24655096
11. King-Stephens D, Mirro E, Weber PB, et al. Lateralization of mesial temporal lobe epilepsy with chronic ambulatory electrocorticography. *Epilepsia*. Jun 2015;56(6):959-967. PMID 25988840
12. Spencer D, Gwinn R, Salinsky M, et al. Laterality and temporal distribution of seizures in patients with bitemporal independent seizures during a trial of responsive neurostimulation. *Epilepsy Res*. Feb 2011;93(2-3):221-225. PMID 21256715
13. Food and Drug Administration. Summary of Safety and Effectiveness Data: RNS System 2013; [https://www.accessdata.fda.gov/cdrh\\_docs/pdf10/P100026b.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100026b.pdf).
14. Fisher RS, Cross JH, French JA, et al. Operational classification of seizure types by the International League Against Epilepsy: Position Paper of the ILAE Commission for Classification and Terminology. *Epilepsia*. Apr 2017;58(4):522-530. PMID 28276060
15. Kwan P, Arzimanoglou A, Berg AT et al. Definition of drug resistant epilepsy: consensus proposal by the ad hoc Task Force of the ILAE Commission on Therapeutic Strategies. *Epilepsia*. 2010 Jun;51(6). PMID 19889013
16. Xue-Ping W, Hai-Jiao W, Li-Na Z et al. Risk factors for drug-resistant epilepsy: A systematic review and meta-analysis. *Medicine (Baltimore)*. 2019 Jul;98(30). PMID 31348240

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17. Neuropace, Inc. RNS(R) System Physician Manual for the RNS(R) Neurostimulator Model RNS-320. Revised February 2020.  
[https://www.neuropace.com/manuals/RNS\\_System\\_Physician\\_Manual.pdf](https://www.neuropace.com/manuals/RNS_System_Physician_Manual.pdf).
18. Morrell MJ, Group RNSSiES. Responsive cortical stimulation for the treatment of medically intractable partial epilepsy. *Neurology*. Sep 27 2011;77(13):1295-1304. PMID 21917777
19. Heck CN, King-Stephens D, Massey AD, et al. Two-year seizure reduction in adults with medically intractable partial onset epilepsy treated with responsive neurostimulation: final results of the RNS System Pivotal trial. *Epilepsia*. Mar 2014;55(3):432-441. PMID 24621228
20. Loring DW, Kapur R, Meador KJ, et al. Differential neuropsychological outcomes following targeted responsive neurostimulation for partial-onset epilepsy. *Epilepsia*. Nov 2015;56(11):1836-1844. PMID 26385758
21. Meador KJ, Kapur R, Loring DW, et al. Quality of life and mood in patients with medically intractable epilepsy treated with targeted responsive neurostimulation. *Epilepsy Behav*. Apr 2015;45:242-247. PMID 25819949
22. Cox JH, Seri S, Cavanna AE. Clinical utility of implantable neurostimulation devices as adjunctive treatment of uncontrolled seizures. *Neuropsychiatr Dis Treat*. Dec 2014;10:2191-2200. PMID 25484587
23. Gooneratne IK, Green AL, Dugan P, et al. Comparing neurostimulation technologies in refractory focal-onset epilepsy. *J Neurol Neurosurg Psychiatry*. Nov 2016;87(11):1174-1182. PMID 27516384
24. Bergey GK, Morrell MJ, Mizrahi EM, et al. Long-term treatment with responsive brain stimulation in adults with refractory partial seizures. *Neurology*. Feb 24 2015;84(8):810-817. PMID 25616485
25. Lee B, Zubair MN, Marquez YD, et al. A single-center experience with the neuropace rns system: a review of techniques and potential problems. *World Neurosurg*. Sep 2015;84(3):719-726. PMID 25940211
26. Child ND, Stead M, Wirrell EC, et al. Chronic subthreshold subdural cortical stimulation for the treatment of focal epilepsy originating from eloquent cortex. *Epilepsia*. Mar 2014;55(3):e18-21. PMID 24571166
27. Morris GL, 3rd, Gloss D, Buchhalter J, et al. Evidence-based guideline update: vagus nerve stimulation for the treatment of epilepsy: report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. Oct 15 2013;81(16):1453-1459. PMID 23986299

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08/01/2019 Medical Policy Committee review

08/14/2019 Medical Policy Implementation Committee approval. New policy.

08/06/2020 Medical Policy Committee review

08/12/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

09/16/2020 Coding update

Next Scheduled Review Date: 08/2021

### **Coding**

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	61850, 61860, 61863, 61864, 61880, 61885, 61886, 61888, 95970, 95971
HCPCS	L8680, L8686, L8688
ICD-10 Diagnosis	G40.001-G40.219 Added codes eff 10/1/2020: G40.42, G40.833, G40.834

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
  - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  - 3. Reference to federal regulations.

\*\*Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;

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- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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