Medical Policy:

Cortical Stimulation for Epilepsy (NeuroPace®)

POLICY NUMBER	LAST REVIEW
MG.MM.SU.69dC	November 8, 2024

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Cortical stimulation	Involves the implantation of electrodes onto the surface the brain near areas associated with seizure activity. One responsive neurostimulation device, the NeuroPace® RNS® System, is currently approved by FDA The system consists of the implant and external components: • The implant is the RNS neurostimulator (generator) and leads (tiny wires containing electrodes connected to the target areas of the brain). The neurostimulator is a battery powered microprocessor-controlled generator that is placed within the skull and beneath the scalp. It connects to one or two leads that are either inserted into the brain (depth lead) or placed on the brain surface in the area of the seizure focus (cortical strip lead). • The external components include the programmer, remote monitor and magnet. The programmer is a laptop computer installed with a proprietary software program, which clinicians use to retrieve information from the neurostimulator and noninvasively program the neurostimulator through telemetry wand. The remote monitor component consists of a laptop computer, proprietary software and a telemetry wand. Using the telemetry wand (by swiping it over the implant site), a patient can transfer information from the neurostimulator to the laptop at home. The magnet allows patients to instruct the neurostimulator to record brain activity when seizure occurs or stop stimulation.

Focal onset seizures (*previously termed partial*)	The term focal is used instead of partial to be more accurate when talking about where seizures begin. Focal seizures can start in one area or group of cells in one side of the brain. • Focal onset aware seizures (*previously termed simple partial seizure*): When a person is awake and aware during a seizure, it's called a focal aware seizure. • Focal onset impaired awareness (*previously termed complex partial seizure*): When a person is confused or their awareness is affected in some way during a focal seizure, it's called a focal impaired awareness seizure.
Medically refractory seizures	Occur despite treatment with therapeutic levels of antiepileptic drugs or seizures that cannot be treated with therapeutic levels of antiepileptic drugs because of intolerable adverse side effects.

Guideline

Cortical stimulation is considered medically for members with epilepsy who are ≥ 18 years of when **all** of the following criteria are met:

1. Intractable focal aware seizures
2. Diagnostic confirmation of ≤ 2 well localized seizure foci identified
3. Refractory to ≥ 2 antiepileptic medications
4. ≥ 3 disabling seizures per month over the most recent 3 months (e.g., types such as motor partial, complex partial and/or secondary generalized)
5. Member is not a VNS candidate secondary to **any**:
    - Presence of a condition related to the recurrent laryngeal nerve on the contralateral side
    - Swallowing problems that may be exacerbated by VNS implantation
    - Obstructive sleep apnea
    - Previous left-sided neck surgery
    - Asthma or chronic obstructive pulmonary disease (COPD) that may be exacerbated by VNS implantation

Limitations and Exclusions

1. Responsive cortical stimulation is considered experimental and investigational for primary generalized seizures and for all other indications.
2. The RNS® System is contraindicated for:
    - Patients at high risk for surgical complications such as active systemic infection, coagulation disorders (such as the use of anti-thrombotic therapies) or platelet count below 50,000
    - Patients who have medical devices implanted that deliver electrical energy to the brain
    - Patients who are unable, or do not have the necessary assistance, to properly operate the NeuroPace® Remote Monitor or magnet

Procedure 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 (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; first array
61864	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; 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
95970	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (ie, cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
95971	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
95978	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, battery status, electrode selectability and polarity, impedance and patient compliance measurements), complex deep brain neurostimulator pulse generator/transmitter, with initial or subsequent programming; first hour
95979	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, battery status, electrode selectability and polarity, impedance and patient compliance measurements), complex deep brain neurostimulator pulse generator/transmitter, with initial or subsequent programming; each additional 30 minutes after first hour (List separately in addition to code for primary procedure)
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension

ICD-10 Diagnoses

G40.011	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, with status epilepticus
G40.019	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, without status epilepticus

G40.111	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, with status epilepticus
G40.119	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, without status epilepticus
G40.211	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, with status epilepticus
G40.219	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, without status epilepticus

References

1. 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
2. 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
3. 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
4. Wiebe S, Blume WT, Girvin JP, et al. A randomized, controlled trial of surgery for temporal-lobe epilepsy. N Engl J Med. 2001;345(5):311-318. PMID 11484687
5. 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
6. 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
7. Fridley J, Thomas JG, Navarro JC, et al. Brain stimulation for the treatment of epilepsy. Neurosurg Focus. Mar 2012;32(3):E13. PMID 22380854
8. Fisher RS. Therapeutic devices for epilepsy. Ann Neurol. Feb 2012;71(2):157-168. PMID 22367987
9. 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
10. 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
11. NeuroPace. RNS System User Manual; Revision Date 04/2015. 2015. http://www.neuropace.com/wp-content/uploads/2015/11/UserManual.pdf. Accessed November 19, 2024.
12. 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
13. 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
14. 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
15. FDA. Summary of Safety and Effectiveness Data: RNS System 2013; http://www.accessdata.fda.gov/cdrh_docs/pdf10/P100026b.pdf. Accessed November 19, 2024.

16. 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
17. 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
18. 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
19. Cox JH, Seri S, Cavanna AE. Clinical utility of implantable neurostimulation devices as adjunctive treatment of uncontrolled seizures. Neuropsychiatr Dis Treat. 2014;10:2191-2200. PMID 25484587
20. 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
21. 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
22. 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
23. 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
24. 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
25. Specialty matched clinical peer review.

Revision History

Nov. 10, 2023	Removed prerequisite stating that the ember must not be a candidate for focal resective epilepsy surgery
Oct. 8, 2021	ConnectiCare, Inc. adopts the clinical criteria of its parent corporation EmblemHealth Removed prerequisite for failed trial of vagus nerve stimulation
Aug. 14, 2020	Added contraindications to Limitations/Exclusions
Sept. 14, 2018	Added clarification that cortical stimulation is considered medically necessary for members with disabling seizures despite surgical intervention