Responsive Neurostimulation for the Treatment of Refractory Partial Epilepsy

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Approved By:	Highmark Health Options – Market Leadership
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Products:	Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 4

Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary responsive neurostimulation for the treatment of refractory partial epilepsy.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

Responsive Neurostimulation (RNS) – Treatment of epilepsy involves the use of one (1) 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 partial epilepsy.

PROCEDURES

1. A prior authorization is required.

RNS may be considered medically necessary for individuals with partial epilepsy who meet ALL of the following criteria:

- Are 18 years of age or older; and
- Have a diagnosis of partial-onset seizures with one (1) or two (2) well-localized seizure foci identified; and
- Have an average of three (3) or more disabling seizures (e.g., motor partial seizures, complex partial seizures, or secondary generalized seizures) per month over the prior three (3) months; and
- Are refractory to medical therapy (have failed two (2) or more appropriate antiepileptic medications at therapeutic doses); and
- Are not candidates for focal resective epilepsy surgery (e.g., have an epileptic focus near eloquent cerebral cortex; have bilateral temporal epilepsy); and
- Do not have any of the following contraindications for RNS placement:
    - Three (3) or more specific seizure foci; or
    - Presence of primary generalized epilepsy; or
    - Presence of a rapidly progressive neurologic disorder.

RNS is considered experimental investigational and therefore noncovered for all other indications because the safety and/or the effectiveness of this service cannot be established by the available published peer reviewed literature.

2. Post-payment audit statement

   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

3. Place of service: inpatient/outpatient

   Experimental/investigational (E/I) services are not covered regardless of place of service.

   Responsive Neurostimulation for the Treatment of Refractory Partial Epilepsy is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a comorbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

CODING REQUIREMENTS

CPT code	Description
61850	Twist drill or burr hole(s) for implantation or 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	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; each additional array (list separately in addition to primary procedure).
61867	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), with use of intraoperative microelectrode recording; first array.
61868	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), with 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 array.
61888	Revision or removal of cranial neurostimulator pulse generator or receiver.
95970	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and 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 (i.e., cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming.

COVERED DIAGNOSIS CODES

Codes						
G40.011	G40.019	G40.111	G40.119	G40.211	G40.219	G40.311
G40.319	G40.411	G40.419	G40.803	G40.804	G40.A11	G40.A19
G40.B11	G40.B19					

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

Reference

Bergey G K, Morrell M J, Mizrahi E M, et al. Seizures long-term treatment with responsive brain stimulation in adults with refractory partial seizures. Neurology. 2015;(84):810-817.

Elder C, Friedman D, Devinsky O, Doyle W, Dugan P. Responsive neurostimulation targeting the anterior nucleus of the thalamus in 3 patients with treatment-resistant multifocal epilspsy. Epilepsia Open. 2019;4:187–192.

Geller EB, Skarpaas TL, Gross RE, et al. Brain-responsive neurostimulation in patients with medically intractable mesial temporal lobe epilepsy. Epilepsia. 2017;58(6):994-1004.

Hayes, Inc. Evidence Analysis Research Brief. NeuroPace RNS system (Neuropace Inc.) for Treatment of Drug-Resistant Epilepsy. Lansdale, PA: Hayes, Inc.; September, 2019.

Jobst BC, Kapur R, Barkley GL, et al. Brain-responsive neurostimulation in patients with medically intractable seizures arising from eloquent and other neocortical areas. Epilepsia. 2017;58(6):1005-14.

Kinnear KM, Warner NM, Gersappe A, Doherty MJ. Pilot data on responsive epilepsy neurostimulation, measures of sleep apnea and continuous glucose measurements. Epilepsy Behav Rep. 2018;9:33-6.

Loring DW, Kapur R, Meador KJ, et al. Differential neuropsychological outcomes following targeted responsive neurostimulation for partial-onset epilepsy. Epilepsia. 2015;56(11):1836-1844.

Starnes K, Miller K, Wong-Kisiel L, Lundstrom BN. A review of neurostimulation for epilepsy in pediatrics. Brain Sci. 2019;9(10):283.

POLICY UPDATE HISTORY

<Date>	<Event>