**Medica Coverage Policy**

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<th>Policy Name:</th>
<th>Implantable Deep Brain and Responsive Cortical Stimulation</th>
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**Important Information – Please Read Before Using This Policy**

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

**Coverage Policy**

**Deep Brain Stimulation**

Deep brain stimulation is **COVERED** when used for the following FDA approved indications:

1. Thalamic stimulation for the suppression of tremor in the upper extremity in patients who are diagnosed with essential tremor or Parkinsonian tremor not adequately controlled by medication and where the tremor constitutes a significant functional disability, or
2. Stimulation of the internal globus pallidus (GPI) or the subthalamic nucleus (STN) as an adjunctive therapy in reducing some of the symptoms of advanced, levodopa-responsive Parkinson’s diseases that are not adequately controlled with medication
3. Intractable primary dystonia.

Deep brain stimulation is considered investigative and unproven and therefore **NOT COVERED** for all other conditions, including, but not limited to: depression, epilepsy, secondary dystonia, cluster headaches, multiple sclerosis, and neuropathic pain. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the safety and efficacy or effects on health care outcomes.

The investigative determination does not apply to HDE approved devices. The following HDE approved devices are covered for the following:

1. The Reclaim™ Deep Brain Stimulation device for obsessive compulsive disorder (OCD)
2. The Activa® Dystonia Therapy device for treatment of primary dystonia.

For a current list of HDE-approved devices, refer to the FDA HDE Database at: [http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm)

**Responsive Cortical Stimulation**

Responsive cortical stimulation for treatment of epilepsy is **COVERED** for treatment of localized focal epilepsy when using an FDA-approved device for individuals 18 years or older with all of the following indications:

1. A diagnosis of one or two well-identified localized seizure foci
2. An average of at least three disabling seizures per month over the prior consecutive three months
3. Refractory to two or more antiepileptic medications.
Responsive cortical stimulation for treatment of epilepsy is considered investigational and unproven and therefore **NOT COVERED** for all other indications. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Note: See also related Medica coverage policies; *Repetitive Transcranial Magnetic Stimulation* and *Vagus Nerve Stimulation*.

**Description**

**Deep Brain Simulation**

Deep brain stimulation consists of electrode(s) implanted into the targeted brain structure (e.g., thalamus, subthalamic nucleus, or globus pallidus). Unilateral or bilateral electrodes are connected to an implantable pulse generator power source and is generally implanted in the subclavicular region of the chest cavity. The electrodes, through a battery-operated neurostimulator, carry a high frequency electrical signal that interferes with the neural activity at the placement site and is thought to inhibit the activity in that region of the brain. The electrode(s) and the generator are connected by an extension wire that is tunneled down the neck under the skin. The device can be turned on and off by the patient using a hand held magnet.

**Responsive Cortical Stimulation**

The RNS® system (NeuroPace, Inc.), also known as Responsive Neuromodulation Stimulation system, is an implanted, intracranial neurostimulator intended for treating epilepsy. The device uses responsive cortical stimulation, which continuously monitors the brain for electrical seizure patterns and delivers electrical pulses to the brain to prevent seizure onset. The RNS system is intended as an alternative to surgical epileptic foci ablation and to other neurostimulation approaches, specifically for patients with seizures not sufficiently controlled by medication. During the procedure, cortical leads are placed on the dura and affixed with sutures, and deep leads are inserted into the brain. The neurostimulator is then placed within the skull near the parietal bone and the leads are connected to the stimulator.

**FDA Approval**

**Deep Brain Stimulation**

Multiple devices have been approved for unilateral and/or bilateral deep brain stimulation for suppression of upper extremity tremor not adequately controlled by medication and where the tremor constitutes a significant functional disability, including but not limited to:

1. Activa® Tremor Control System (Medtronic)
2. Brio™ Neurostimulation System (St. Jude Medical)
3. Infinity™ Deep Brain Stimulation System (St. Jude Medical).

Multiple devices have been approved for bilateral deep brain stimulation as an adjunctive therapy in reducing symptoms of advanced, levodopa-responsive Parkinson’s diseases that are not adequately controlled with medication, including but not limited to:

1. Activa® Tremor Control System (Medtronic)
2. Brio™ Neurostimulation System (St. Jude Medical)

**Responsive Cortical Stimulation**

The FDA granted premarket approval (PMA P100026) to the RNS System (NeuroPace, Inc) in November 2013 as adjunctive therapy in reducing frequency of seizures in individuals who:

1. Are at least 18 years of age with partial onset seizures
2. Have undergone diagnostic testing that localized no more than 2 epileptogenic foci
3. Are refractory to two or more antiepileptic medications
4. Currently have frequent and disabbling seizures.
Prior Authorization
Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

Coding Considerations
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

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 (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)
- **61867** - 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), 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 (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; each additional array (List separately in addition to primary procedure)
- **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