Medica Central Coverage Policy

Policy Name:	**Implantable Deep Brain and Responsive Cortical Stimulation**
Effective Date:	**11/01/2023**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica Central plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other 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, Medicaid, and other government programs, this policy will apply unless these 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 may call the Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number. https://mo-central.medica.com/Providers/SSM-employee-health-plan-for-IL-MO-OK-providers

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

NOTE: This policy *does not* address behavioral health indications (e.g., major depressive disorder, schizophrenia, etc.). For questions specific to behavioral health indications for all members please contact the service provider listed on the back of your member card.

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
4. Medically refractory epilepsy.

Deep brain stimulation is considered investigative and unproven and therefore **NOT COVERED** for all other conditions, including, but not limited to: 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 device is covered for primary dystonia:

1. The Activa® Dystonia Therapy Device

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

Responsive Cortical Stimulation

Responsive cortical stimulation for treatment of epilepsy is **COVERED** for treatment of localized focal epilepsy when used for the following FDA approved 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 investigative 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 policy, *Transcranial Magnetic Stimulation*

Description

Deep Brain Stimulation

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 handheld 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)
3. Vercise™ Deep Brain Stimulation System (Boston Scientific).

In 2018, the FDA approved the Medtronic Activa DBS System for epilepsy for bilateral stimulation of the anterior nucleus of the thalamus) as an adjunctive therapy for reducing the frequency of seizures in individuals 18 years of age or older diagnosed with epilepsy that are:

1. Characterized by partial-onset seizures, with or without secondary generalization, and
2. Refractory to three or more anti-epileptic medications.

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 least18 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 disabling 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

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