Deep Brain and Cortical Stimulation (for North Carolina Only)

Policy Number: CSNCT0321.04
Effective Date: May 1, 2023

Instructions for Use

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Related Policy

- Vagus and External Trigeminal Nerve Stimulation (for North Carolina Only)

Application

This Medical Policy only applies to the state of North Carolina.

Coverage Rationale

Deep brain stimulation (DBS) is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the North Carolina Medicaid (Division of Health Benefits) Clinical Coverage Policy for Physician, 1A-26, Deep Brain Stimulation.

Responsive cortical stimulation is proven and medically necessary for treating refractory partial or focal seizure disorder.

For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Stereotactic Introduction, Subcortical or Cortical Electrodes.

Click here to view the InterQual® criteria.

The following are unproven and not medically necessary due to insufficient evidence of efficacy:

- Responsive cortical stimulation for treating obsessive-compulsive disorder (OCD) and for all other indications not listed above.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
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 (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)
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
64999	Unlisted procedure, nervous system

HCPCS Code	Description
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8682	Implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension

Description of Services

Deep Brain Stimulation

Deep brain stimulation (DBS) delivers electrical pulses to select areas of the brain (e.g., the internal globus pallidus interna (GPi), subthalamic nucleus (STN) or ventral intermediate nucleus (VIM) of the thalamus) via surgically implanted electrodes. The mechanism of action is not completely understood, but the goal of DBS is to interrupt the pathways responsible for the abnormal movements associated with movement disorders such as Parkinson's disease and essential tremor. The exact location of electrodes depends on the type of disorder being treated, and unlike standard surgical ablation, which causes permanent destruction of the targeted area, DBS is reversible and adjustable. The DBS device consists of an implantable pulse generator (IPG) or neurostimulator, an implantable lead with electrodes and a connecting wire. The neurostimulator is approximately the size of a stopwatch and is similar to a cardiac pacemaker. Subcutaneous extension wires connect the lead(s) to the neurostimulator which is implanted near the clavicle or, in the case of younger individuals with primary dystonia, in the abdomen.

Responsive Cortical Stimulation (Closed-Loop Implantable Neurostimulator)

The RNS® System (NeuroPace, Inc.) is intended to detect abnormal electrical brain signals that precede seizures and deliver electrical stimulation in response to try to normalize electrical brain activity and prevent seizures. The device includes a neurostimulator that is placed in the skull and leads that are placed in the seizure-originating areas of the brain. The system's intended benefits include seizure prevention, fewer adverse events than other neurostimulation methods, and data transmission from the individual's home to clinicians.

Clinical Evidence

Responsive Cortical Stimulation

There is insufficient evidence to support Responsive Cortical Stimulation for treating indications other than partial or focal seizure disorders due to the lack of clinical studies. Large well- designed studies are needed to establish safety, efficacy and long-term outcomes.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Deep Brain Stimulation

Deep brain and cortical stimulation is a procedure and, therefore, not subject to FDA regulation. However, any medical devices, drugs, and/or tests used as part of this procedure may require FDA regulation.

On September 19, 2016, the FDA approved a Premarket Approval (PMA) application bundles supplement (P140009/S001) approving the use of the St. Jude Medical Infinity™ DBS System. The FDA approval for the Infinity DBS System is a supplement to an earlier PMA (P140009) for the St. Jude Medical Brio Neurostimulation system. According to the manufacturer, the Infinity DBS System and the Brio Neurostimulation System have the same indications for use. Refer to the following website for more information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140009. (Accessed October 10, 2022)

On December 8, 2017, the FDA approved a Premarket Approval (PMA) application (P150031) for the Vercise™ Deep Brain Stimulation (DBS) System (Boston Scientific). Refer to the following website for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_template.cfm?id=p150031. (Accessed October 10, 2022)

Other Indications

On March 28, 2005, the Activa® Deep Brain Stimulation Therapy System was designated as a Humanitarian Use Device (HUD) for the treatment of chronic, treatment-resistant obsessive-compulsive disorder (OCD) in a subset of patients. However, the FDA does not list a Humanitarian Device Exemption (HDE) approval for authorization to market the device.

On February 19, 2009, the Reclaim™ Deep Brain Stimulation Therapy device was designated as a HUD for the treatment of obsessive-compulsive disorder (OCD). This device is indicated for bilateral stimulation of the anterior limb of the internal capsule (AIC) as an adjunct to medications and as an alternative to anterior capsulotomy for treatment of chronic, severe, treatment-resistant OCD in adult patients who have failed at least three selective serotonin reuptake inhibitors (SSRIs). Refer to the following website for more information: https://www.accessdata.fda.gov/cdrh_docs/pdf5/H050003a.pdf. (Accessed October 10, 2022)

Responsive Cortical Stimulation

The FDA approved the NeuroPace RNS Neurostimulator System on November 14, 2013. The device is indicated as 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 two 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 three 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.

The RNS System is contraindicated for:

- Patients with risk factors for surgical complications such as active systemic infection, coagulation disorders (such as the use of antithrombotic therapies), or platelet count below 50,000
- Patients who have implanted medical devices 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

The following medical procedures are contraindicated for patients with an implanted RNS System. The procedures may send energy through the implanted brain stimulation system causing permanent brain damage, which may result in severe injury, coma, or death. Brain damage can occur from any of the listed procedures even if the RNS neurostimulator is turned off, the leads are not connected to the neurostimulator, or the neurostimulator has been removed and any leads (or any part of a lead) remain:

- MRI
- Diathermy procedures (high-frequency electromagnetic radiation, electric currents, or ultrasonic waves used to produce heat in body tissues) (Patients should not be treated with any type of shortwave, microwave, or therapeutic ultrasound diathermy device, on any part of the body, regardless of whether the device is used to produce heat.)
- Electroconvulsive therapy
- Transcranial magnetic stimulation

Refer to the following website for more information:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P100026. (Accessed October 10, 2022)

Additional Products

- Activa® Tremor Control Therapy (Medtronic, Inc.)
- Activa® Parkinson's Control Therapy (Medtronic, Inc.)
- Activa® Dystonia Therapy (Medtronic, Inc.)
- Kinetra® Neurostimulator (Medtronic, Inc.)
- Soletra® Neurostimulator (Medtronic, Inc.)

References

North Carolina Medicaid, Division of Health Benefits, Clinical Coverage Policies, Deep Brain Stimulation (DBS) No: 1A-26. https://medicaid.ncdhhs.gov/media/7861/open. Accessed December 6, 2022.

Policy History/Revision Information

Date	Summary of Changes

05/01/2023	**Coverage Rationale**
	Responsive Cortical Stimulation
	• Revised language to indicate:
	  ○ Responsive cortical stimulation is proven and medically necessary for treating refractory partial or focal seizure disorder; for medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Stereotactic Introduction, Subcortical or Cortical Electrodes
	  ○ Responsive cortical stimulation for treating obsessive-compulsive disorder (OCD) and for all other indications not listed [in the policy as proven and medically necessary] are unproven and not medically necessary due to insufficient evidence of efficacy
	Supporting Information
	• Added *Description of* Services, *Clinical Evidence*, and *FDA* sections
	• Updated *References* section to reflect the most current information
	• Archived previous policy version CSNCT0321.03

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies 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.