

Instructions for Use

Deep Brain and Cortical Stimulation (for North Carolina Only)

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Related Policy

• <u>Vagus and External Trigeminal Nerve Stimulation</u> (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 <u>North Carolina Medicaid (Division of Health Benefits) Clinical Coverage Policy</u>, <u>Physician: 1A-26, Deep Brain Stimulation</u>.

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

For medical necessity clinical coverage criteria for deep brain and responsive cortical stimulation, 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

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

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CPT Code	Description
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

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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

Codes labeled with an asterisk (*) are not on the State of North Carolina Medicaid Fee Schedule and therefore may not be covered by the State of North Carolina Medicaid Program.

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 before they fully develop. The device includes a neurostimulator that is placed in the skull and leads that are placed in the seizureoriginating 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.

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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.

For information on deep brain stimulation devices refer to the following website (use product codes MHY, NHL, OLM and OLX): <u>http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm</u>. (Accessed January 6, 2025).

For information on responsive cortical devices refer to the following website (use product code PFN): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed January 6, 2025)

References

North Carolina Medicaid, Division of Health Benefits, Clinical Coverage Policies, Deep Brain Stimulation (DBS), 1A-26. Available at: <u>https://medicaid.ncdhhs.gov/1a-26-deep-brain-stimulation/download?attachment</u>. Accessed January 6, 2025.

Policy History/Revision Information

Date	Summary of Changes
04/01/2025	Coverage Rationale
	Updated instruction to refer to the InterQual [®] CP: Procedures, Stereotactic Introduction, Subcortical or Cortical Electrodes for medical necessity clinical coverage criteria <i>for deep brain</i> <i>and responsive cortical stimulation</i>
	Applicable Codes
	• Added notation to indicate HCPCS codes L8679, L8680, L8682, L8685, L8686, L8687, and L8688 are not on the State of North Carolina Medicaid Fee Schedule and therefore may not be covered by the State of North Carolina Medicaid Program
	Supporting Information
	Updated Description of Services and FDA sections to reflect the most current information
	Archived previous policy version CSNCT0321.05

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.