Deep brain stimulation is proven and medically necessary for treating the following indications:

- Dystonia
- Essential Tremor
- Parkinson’s disease
- Refractory Epilepsy

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

For medical necessity clinical coverage criteria, refer to the InterQual® 2021, Apr. 2021 Release, 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:

- Deep brain stimulation and cortical stimulation for treating obsessive-compulsive disorder (OCD) and for all other indications not listed above.
- Responsive cortical stimulation for treating all other indications not listed above.
### Deep Brain and Cortical Stimulation

<table>
<thead>
<tr>
<th>CPT/HCPCS Codes*</th>
<th>Required Clinical Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>61863</td>
<td>Medical notes documenting the following, when applicable:</td>
</tr>
<tr>
<td>61864</td>
<td>• Diagnosis</td>
</tr>
<tr>
<td>61867</td>
<td>• Specify specific procedure</td>
</tr>
<tr>
<td>61868</td>
<td>• History of the medical condition(s) requiring treatment or surgical intervention, including condition interference with activity of daily living</td>
</tr>
<tr>
<td>61885</td>
<td>• Documentation of signs and symptoms; including onset, duration, and frequency, including seizures history including number of seizures per month</td>
</tr>
<tr>
<td>61886</td>
<td>• Physical exam</td>
</tr>
<tr>
<td>L8679</td>
<td>• Relevant medical history, including:</td>
</tr>
<tr>
<td>L8680</td>
<td>• Medical co-morbidities</td>
</tr>
<tr>
<td>L8682</td>
<td>• Psychiatric co-morbidities</td>
</tr>
<tr>
<td>L8685</td>
<td>• Treatments tried, failed, or contraindicated; include the dates and reason for discontinuation</td>
</tr>
<tr>
<td>L8686</td>
<td>• Current medications used to treat condition, include start date</td>
</tr>
<tr>
<td>L8687</td>
<td>• Relevant surgical history, including previous movement disorder surgery and dates</td>
</tr>
<tr>
<td>L8688</td>
<td>• Reports of all recent imaging studies and applicable diagnostics, including:</td>
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<tr>
<td></td>
<td>• Results of imaging for skeletal deformities and cervical myelopathy</td>
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<td></td>
<td>• Results of brain MRI</td>
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<td></td>
<td>• Results of video electroencephalographic (EEG) monitoring</td>
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<td></td>
<td>• Results of levodopa challenge</td>
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<tr>
<td></td>
<td>• Results of Yale-Brown Obsessive-Compulsive Scale (Y-BOCS)</td>
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<tr>
<td></td>
<td>• Physician treatment plan, including:</td>
</tr>
<tr>
<td></td>
<td>• Member understanding of surgical risk, complications and need for follow-up</td>
</tr>
<tr>
<td></td>
<td>• Planned placement of electrodes for preoperative mapping</td>
</tr>
</tbody>
</table>

*For code descriptions, see the [Applicable Codes](#) section.

### 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 the member specific benefit plan document 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.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>61850</td>
<td>Twist drill or burr hole(s) for implantation of neurostimulator electrodes, cortical</td>
</tr>
<tr>
<td>61860</td>
<td>Craniectomy or craniotomy for implantation of neurostimulator electrodes, cerebral, cortical</td>
</tr>
<tr>
<td>61863</td>
<td>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</td>
</tr>
<tr>
<td>61864</td>
<td>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)</td>
</tr>
<tr>
<td>61867</td>
<td>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</td>
</tr>
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</table>
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.

Benefit Considerations

In certain benefit documents (for example, the 2001 Certificate of Coverage), Humanitarian Use Devices (HUDs) require Institutional Review Board (IRB) oversight and are considered to be investigational and not covered. In other benefit documents (for example, the 2007 Certificate of Coverage and subsequent versions), HUDs are not considered to be investigational and are covered when used for proven indications. Consult the member specific benefit plan document for details.
**Clinical Evidence**

**Deep Brain Stimulation**

**Obsessive Compulsive Disorder (OCD)**

Due to limited studies, small sample sizes, weak study designs and heterogenous study population characteristics, there is insufficient data to conclude that deep brain stimulation is safe and/or effective for treating obsessive-compulsive disorder (OCD).

Hageman et al. (2021) performed a meta-analysis comparing the clinical outcomes of the ablative procedures capsulotomy and cingulotomy and deep brain stimulation (DBS). Ablative surgery (ABL) and DBS are last-resort treatment options for patients suffering from treatment-refractory obsessive-compulsive disorder (OCD). A PubMed search was used to identify all clinical trials on capsulotomy, cingulotomy and DBS. Random effects meta-analyses were performed on 38 articles with a primary focus on efficacy in reducing OCD symptoms as measured by a reduction in the Yale-Brown Obsessive Compulsive Scale (Y-BOCS) score and the responder rate (≥35% reduction in Y-BOCS score). With responder rates of 48% and 53% after 12-16 months and 56% and 57% at last follow-up for ABL and DBS, respectively, and large effect-sizes in the reduction in YBOCS scores, both surgical modalities show effectiveness in treating refractory OCD. Meta-regression did not show a statistically significant difference between ABL and DBS regarding these outcomes. Regarding adverse events, a statistically significant higher rate of impulsivity is reported in studies on DBS. This meta-analysis shows equal efficacy of ABL and DBS in the treatment of refractory OCD. For now, the choice of intervention should, therefore, rely on factors such as risk of developing impulsivity, patient preferences and experiences of psychiatrist and neurosurgeon. Additional research is needed to provide a better understanding regarding differences between ABL and DBS and response prediction following direct comparisons between the surgical modalities, to enable personalized and valid choices between ABL and DBS. The safety and efficacy of these techniques must be studied more thoroughly before wider clinical application.

Vázquez-Bourgon et al. (2019) systematically reviewed the literature to identify the main characteristics of DBS, its use and applicability as treatment for OCD. According to the authors, the critical analysis of the evidence showed that the use of DBS in treatment-resistant OCD is providing satisfactory results regarding efficacy, with assumable side-effects. However, there is insufficient evidence to support the use of any single brain target over another. Patient selection has to be done following analyses of risks/benefits, being advisable to individualize the decision of continuing with concomitant psychopharmacological and psychological treatments. The authors concluded that the use of DBS is still considered to be in the field of research, although it is increasingly used in refractory-OCD, producing in the majority of studies significant improvements in symptomatology, and in functionality and quality of life. Random and controlled studies need to be done to determine its long-term efficacy.

Rapinesi et al. (2019) conducted a systematic review to assess the effect of brain stimulation techniques in OCD. DBS showed best results when targeting the crossroad between the nucleus accumbens and the ventral capsule or the subthalamic nucleus. The authors concluded that different brain stimulation techniques are promising as an add-on treatment of refractory OCD, although studies frequently reported inconsistent results. DBS could possibly find some use with adequate testing, but its standard methodology still needs to be established. The authors indicated that the review was limited because of the inclusion of methodologically inconsistent underpowered studies.

In a systematic review, Naesström et al. (2016) reviewed the current studies on psychiatric indications for DBS, with focus on OCD and major depressive disorder (MDD). A total of 52 studies met the inclusion criteria with a total of 286 unique patients treated with DBS for psychiatric indications; 18 studies described 112 patients treated with DBS for OCD in six different anatomical targets, while nine studies included 100 patients with DBS for MDD in five different targets. The authors concluded that DBS may show promise for treatment-resistant OCD and MDD but the results are limited by small sample size and insufficient randomized controlled data. According to the authors, other psychiatric indications are currently of a purely experimental nature.

Hamani et al. (2014) conducted a systematic review of the literature and developed evidence-based guidelines on DBS for OCD that was sponsored by the American Society for Stereotactic and Functional Neurosurgery and the Congress of Neurological Surgeons (CNS) and endorsed by the CNS and American Association of Neurological Surgeons. Of 353 articles identified, 7 were retrieved for full-text review and analysis. The quality of the articles was assigned to each study and the strength of
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.

Deep Brain Stimulation

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. See the following website for more information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140009. (Accessed August 24, 2021)

On December 8, 2017, the FDA approved a Premarket Approval (PMA) application (P150031) for the Vercise™ Deep Brain Stimulation (DBS) System (Boston Scientific). See the following website for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_template.cfm?id=p150031. (Accessed August 24, 2021)

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

See the following website for more information:

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
Policy History/Revision Information

<table>
<thead>
<tr>
<th>Date</th>
<th>Summary of Changes</th>
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</table>
| 11/01/2021 | **Coverage Rationale**  

**Deep Brain Stimulation**  
- Revised language to indicate deep brain stimulation is proven and medically necessary for treating the following indications:  
  o Dystonia  
  o Essential tremor  
  o Parkinson’s disease  
  o Refractory epilepsy  
- Removed language indicating directional deep brain stimulation that enables specific steering of current towards targeted lesions is unproven and not medically necessary for treating any condition including but not limited to dystonia, Parkinson’s disease, or tremor  
- Replaced language indicating “conventional deep brain stimulation is unproven and not medically necessary for treating obsessive-compulsive disorder (OCD) and for all other indications not listed [in the policy as proven and medically necessary]” with “deep brain stimulation is unproven and not medically necessary for treating obsessive-compulsive disorder (OCD) and for all other indications not listed [in the policy as proven and medically necessary]”  

**Documentation Requirements**  
- Updated list of applicable HCPCS codes with associated documentation requirements; added L8679  

**Supporting Information**  
- Updated Description of Services, Clinical Evidence, FDA, and References sections to reflect the most current information  
- Archived previous policy version 2021T0321Z

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. 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.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

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