

# Deep Brain and Cortical Stimulation (for Ohio Only)

Policy Number: CS030OH.K – P  
Effective Date: February 1, 2023

[Instructions for Use](#)

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**Related Policy**

- [Vagus and External Trigeminal Nerve Stimulation \(for Ohio Only\)](#)

## Application

This Medical Policy only applies to the state of Ohio.

## Coverage Rationale

### Deep Brain Stimulation

Conventional deep brain stimulation is proven and medically necessary for treating the following indications (this does not apply to Directional deep brain stimulation):

- 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® 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:

- Conventional deep brain stimulation and cortical stimulation for treating obsessive-compulsive disorder (OCD) and for all other indications not listed above.
- Directional deep brain stimulation that enables specific steering of current towards targeted lesions for treating any condition including but not limited to:
  - Dystonia
  - Parkinson’s disease
  - Tremor
- Responsive cortical stimulation for treating 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 two or more electrode arrays
64999	Unlisted procedure, nervous system

*CPT® is a registered trademark of the American Medical Association*

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

Conventional 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. Conventional deep brain stimulation systems deliver stimulation using cylindrical electrodes or Ring Mode (omnidirectional) stimulation, which stimulate neurons around the entire circumference of the lead.

Directional deep brain stimulation uses a directional lead designed to steer electrical current to relevant areas of the brain while avoiding areas that may cause side effects. Several independent electrode contacts can be programmed, creating a more customized therapy. The St. Jude Medical Infinity™ DBS System (Abbott) and the Vercise™ Deep Brain Stimulation System (Boston Scientific) are DBS systems with directional leads.

### **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**

### **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 ( $\geq 35\%$  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 recommendation graded according to the guideline's development methodology of the American Association of Neurological Surgeons/Congress of Neurological Surgeons Joint Guidelines Committee. Of the 7 studies, 1 class I and 2 class II double-blind, randomized, controlled trials reported that bilateral DBS is more effective in improving OCD symptoms than sham treatment. The authors concluded that based on the data published in the literature, the following recommendations can be made: (1) There is Level I evidence, based on a single class I study, for the use of bilateral subthalamic nucleus DBS for the treatment of medically refractory OCD. (2) There is Level II evidence, based on a single class II study, for the use of bilateral nucleus accumbens DBS for the treatment of medically refractory OCD. (3) There is insufficient evidence to make a recommendation for the use of unilateral DBS for the treatment of medically refractory OCD. The authors noted that additional research is needed to determine which patients respond to deep brain stimulation and if specific targets may be more suitable to treat a specific set of symptoms.

## Directional Deep Brain Stimulation

There is limited evidence comparing directional DBS with traditional DBS methods of stimulation. Long-term follow-up of large cohorts or RCTs comparing directional DBS to standard DBS are needed to determine the effectiveness and long-term results of directional DBS.

Shao et al. (2019) compared six-month outcomes between 42 newer generation and legacy leads implanted in 28 patients. Two cohorts each included 7 Parkinson's disease (PD) patients with bilateral subthalamic nucleus (STN) stimulation and 7 essential tremor (ET) patients with unilateral ventral intermediate nucleus (VIM) stimulation of the thalamus. All directional leads included 6172 Infinity 8-Channel Directional leads and Infinity internal pulse generators and nondirectional leads included lead 3389 with Activa SC for VIM and PC for STN. Six-month outcomes for medication reduction and motor score improvements between new and legacy DBS systems in PD and ET patients were similar. Directionality was employed in 1/3 of patients. Therapeutic window (difference between amplitude when initial symptom relief was obtained and when intolerable side effects appeared with the contact being used) was significantly greater in new DBS systems in both PD and ET patients. The authors concluded that the therapeutic window of newer systems, whether or not directionality was used, was significantly greater than that of the legacy system, which suggests increased benefit and programming options. Improvements in hardware and programming interfaces in the newer systems may also contribute to wider therapeutic windows. The study did not confirm the utility of such findings in improving care and outcome of patients.

In a prospective, double-blind trial, Dembek et al. (2017) investigated whether directional DBS of the subthalamic nucleus in Parkinson's disease (PD) offers increased therapeutic windows, side-effect thresholds, and clinical benefit. In 10 patients, 20 monopolar reviews were conducted to identify the best stimulation directions and compare them to conventional circular DBS. In addition, circular and best-directional DBS were directly compared in a short-term crossover. Motor outcome was also assessed after an open-label follow-up of 3 to 6 months. Stimulation in the individual best direction resulted in significantly larger therapeutic windows, higher side-effect thresholds, and more improvement in hand rotation than circular DBS. Rigidity and finger tapping did not respond differentially to the stimulation conditions. There was no difference in motor efficacy or

stimulation amplitudes between directional and circular DBS in the short-term crossover. Follow-up evaluations 3 to 6 months after implantation showed improvements in motor outcome and medication reduction comparable to other DBS studies with a majority of patients remaining with a directional setting. The authors concluded that directional DBS can increase side-effect thresholds while achieving clinical benefit comparable to conventional DBS. However, the question of whether directional DBS improves long-term clinical outcome needs to be investigated in the future.

Timmermann et al. (2015) conducted a prospective, multicentre, non-randomized, open-label intervention study of an implantable DBS device (Vercise PC System that uses a steerable axial shaping of the electrical stimulation field) at six specialist DBS centers at universities in six European countries. Patients were included if they were aged 21-75 years and had been diagnosed with bilateral idiopathic Parkinson's disease with motor symptoms for more than 5 years. Participants underwent bilateral implantation in the subthalamic nucleus of a multiple-source, constant-current, eight-contact, rechargeable DBS system, and were assessed 12, 26, and 52 weeks after implantation. The primary endpoint was the mean change in unified Parkinson's disease rating scale (UPDRS) III scores (assessed by site investigators who were aware of the treatment assignment) from baseline (medication-off state) to 26 weeks after first lead implantation (stimulation-on, medication-off state). Of 53 patients enrolled in the study, 40 received a bilateral implant in the subthalamic nucleus and their data contributed to the primary endpoint analysis. Improvement was noted in the UPDRS III motor score 6 months after first lead implantation compared with baseline, with a mean difference of 23.8. One patient died of pneumonia 24 weeks after implantation, which was judged to be unrelated to the procedure. 125 adverse events were reported, the most frequent of which were dystonia, speech disorder, and apathy. 18 serious adverse events were recorded, three of which were attributed to the device or procedure (one case each of infection, migration, and respiratory depression). All serious adverse events resolved without residual effects and stimulation remained on during the study. The authors concluded that the multiple-source, constant-current, eight-contact DBS system suppressed motor symptoms effectively in patients with Parkinson's disease, with an acceptable safety profile. According to the authors, future trials are needed to investigate systematically the potential benefits of this system on postoperative outcome and its side-effects. This study was funded by Boston Scientific.

## 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 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.

### Directional 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 January 28, 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](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_template.cfm?id=p150031). (Accessed January 28, 2021)

### 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 an 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). See the following website for more information: [https://www.accessdata.fda.gov/cdrh\\_docs/pdf5/H050003a.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf5/H050003a.pdf). (Accessed January 28, 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:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P100026>. (Accessed October 10, 2019)

## Additional Products

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

## References

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## Policy History/Revision Information

Date	Summary of Changes
02/01/2023	<ul style="list-style-type: none"><li>Created state-specific policy version</li></ul>
07/01/2021	<b>Coverage Rationale</b> <ul style="list-style-type: none"><li>Replaced reference to "InterQual® 2020" with "InterQual® 2021"</li></ul> <b>Supporting Information</b> <ul style="list-style-type: none"><li>Archived previous policy version CS030.J</li></ul>

## 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.