

# Deep Brain and Cortical Stimulation (for Ohio Only)

**Policy Number:** CS030OH.C

**Effective Date:** May 1, 2025

[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. Any requests for services that are stated as unproven or services for which there is a coverage or quantity limit will be evaluated for medical necessity using Ohio Administrative Code 5160-1-01.

## Coverage Rationale

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

- Dystonia
- Essential tremor
- Parkinson's disease
- Refractory epilepsy for a partial or focal seizure disorder

**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:**

- Deep brain stimulation and cortical stimulation for treating obsessive-compulsive disorder (OCD) and all other indications
- Responsive cortical stimulation for treating 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
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
61889	Insertion of skull-mounted cranial neurostimulator pulse generator or receiver, including craniectomy or craniotomy, when performed, with direct or inductive coupling, with connection to depth and/or cortical strip electrode array(s)
61891	Revision or replacement of skull-mounted cranial neurostimulator pulse generator or receiver with connection to depth and/or cortical strip electrode array(s)
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

## 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 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)***

There is insufficient evidence to support the use of deep brain and cortical stimulation for obsessive-compulsive disorder due to study limitations. Larger studies are needed to establish safety, efficacy and long-term outcomes.

Mazzoleni et al. (2023) performed a systematic review aimed to identify relevant guidelines and assess their recommendations for the use of DBS in OCD. The second aim was to determine whether treatment recommendations were adapted to individual traits, such as age, gender and other comorbidities. Out of 532 papers, nine guidelines were identified. Three guidelines scored > 80% on AGREE II. 'Scope and Purpose' and 'Editorial Independence' were the highest scoring domains, but 'Applicability' scores were low. Eight guidelines recommended that DBS be used after all other treatment options have failed to alleviate OCD symptoms. One guideline did not recommend DBS beyond a research setting. The other eight did not provide details on safe or effective DBS protocols. The authors note that while the articles supported the use of DBS for OCD as a last line of therapy, there was a lack of information on many aspects of treating DBS. They indicated further high-quality studies are needed before DBS can be a generalized treatment for OCD.

Gadot et al. (2022) in a recent systematic review and meta-analysis assessing the efficacy of DBS in alleviating obsessive-compulsive disorder (OCD) and comorbid depressive symptoms across targets in patients with treatment-resistant OCD (TROCD). Authors included studies reporting primary data on multiple patients who received DBS therapy with outcomes reported through the Yale-Brown Obsessive-Compulsive Scale (Y-BOCS). Primary effect measures included Y-BOCS mean difference and per cent reduction as well as responder rate ( $\geq 35\%$  Y-BOCS reduction) at last follow-up. Secondary effect measures included standardized depression scale reduction. Thirty-four studies from 2005 to 2021, 9 RCTs ( $n = 97$ ) and 25 non-RCTs ( $n = 255$ ), were included in systematic review and meta-analysis based on available outcome data. A random-effects model indicated a meta-analytical average 14.3 point or 47% reduction ( $p < 0.01$ ) in Y-BOCS scores without significant difference between RCTs and non-RCTs. At last follow-up, 66% of patients were full responders to DBS therapy. Sensitivity analyses indicated a low likelihood of small study effect bias in reported outcomes. Secondary analysis revealed a 1 standardized effect size (Hedges'  $g$ ) reduction in depressive scale symptoms. While these results are encouraging, it is important to remember that DBS does not go without limitations. The main limitation is DBS requires chronic implantation of hardware and carries the risk of complications. Authors note that the discoveries support DBS as an effective treatment for TROCD, and the average appropriately selected patient who experience OCD a 50% decrease in symptoms. Two thirds of patients will achieve at least a full response to DBS therapy with continued follow-up. Stimulation of current limbic and non-limbic targets can provide considerable relief of comorbid depressive symptoms in TROCD. The rising evidence base reporting DBS for OCD outcomes reveals a predominantly low risk of bias across studies. Upcoming crossover RCTs should aim to consistently include washout periods between active and sham stimulation periods, while observational and open-label clinical studies should aim to minimize potential confounders of treatment response and maintain longer follow-up protocols.

Mosley et al. (2021) in a randomized, double-blind, sham-controlled trial investigated the effects of DBS at the bed nucleus of the stria terminalis in a sample of 9 Australian participants (mean age  $47.9 \pm 10.7$  years) with severe, treatment-resistant OCD. After a 1-month postoperative recovery phase, participants entered a 3-month randomized phase during which their stimulators were either turned on or remained switched off. After this, participants entered a 12-month open-label stimulation phase incorporating a course of cognitive behavioral therapy (CBT). The primary outcome measure was OCD symptom severity as assessed by Y-BOCS score. In the blinded phase, there was a significant benefit of active stimulation over sham ( $p = 0.025$ , mean difference 4.9 points). One participant developed an acute implantation effect assessed by a reduction in the intensity of obsessive thoughts for 72 hours postoperatively before returning to baseline. One participant did not reach the target amplitude of 4.5 Volts during the blinded phase due to mild agitation at higher amplitudes, but due to a robust observed symptom reduction, a lower amplitude was selected for chronic stimulation. One participant showed a placebo response to sham stimulation with a 20% reduction in Y-BOCS. After the open phase, the mean reduction in Y-BOCS was  $17.4 \pm 2.0$  points ( $\chi^2 (11) = 39.9$ ,  $p = 3.7 \times 10^{-5}$ ), with 7 participants classified as responders. The addition of CBT resulted in a further Y-BOCS reduction of  $4.8 \pm 3.9$  points ( $p = 0.011$ ). There were nine serious adverse effects affecting four participants. Five of these nine were from one participant that was a non-responder.

and required hospitalization for persistent psychiatric symptoms. There were two serious adverse events related to the DBS device, the most severe of which was an infection during the open phase necessitating device removal. The other device related serious adverse event required re-siting of a DBS electrode that migrated from target implantation. There were no serious psychiatric adverse events related to stimulation. All participants required replacement of the implantable generator due to battery depletion during the study. The authors noted that while this is a promising treatment for severe resistant the small sample size as a limitation of the trial, though it is consistent with other clinical trials of DBS for treatment-resistant psychiatric indications. The study is also limited by the short duration of its blinded phase and lack of long-term follow-up.

Mar-Barrutia et al. (2021) conducted a systematic review to summarize the existing knowledge on the efficacy and tolerability of DBS in treatment-resistant OCD and to compare the short-term (ST) and long-term (LT) results. A comprehensive search was conducted in the PubMed, Cochrane, Scopus, and ClinicalTrials.gov databases from start to December 31, 2020. Inclusion criteria included a main diagnosis of OCD, DBS conducted for therapeutic purposes and variation in symptoms of OCD measured by the Yale-Brown Obsessive-Compulsive scale (Y-BOCS) as primary outcome. Forty articles identified by the search strategy met the eligibility criteria to include 344 patients. Applying a follow-up threshold of 36 months, 29 studies (with 230 patients) provided information on short-term (ST) response to DBS in, while 11 (with 155 patients) reported results on LT response. Mean follow-up period was  $18.5 \pm 8.0$  months for the ST studies and  $63.7 \pm 20.7$  months for the LT studies. Overall, the percentage of reduction in Y-BOCS scores was similar in ST (47.4%) and LT responses (47.2%) to DBS, but more patients in the LT reports met the criteria for response (defined as a reduction in Y-BOCS scores  $> 35\%$ : ST, 60.6% vs. LT, 70.7%). According to the results, the first year predicts the extent to which an OCD patient will benefit from DBS, since the maximum symptom reduction was achieved in most responders in the first 12-14 months after implantation. Reports indicate a consistent tendency for this early improvement to be maintained to the mid-term for most patients; but it is still debatable whether this improvement continues, increases or decreases in the long term. Three different patterns of LT response occurred from the analysis: 49.5% of patients had good and sustained response to DBS, 26.6% were non responders, and 22.5% were partial responders, who might improve at some point but experience relapses during follow-up. There was an improvement in depressive symptoms and global functionality was observed in most studies, usually corresponding with an improvement in obsessive symptoms. Most adverse effects of DBS were mild and transient and improved after adjusting stimulation parameters; however, some severe adverse events including intracranial hemorrhages and infections. Hypomania was the most frequently reported psychiatric side effect. The relationship between DBS and suicide risk remains controversial and requires further study. There are no clear clinical or biological predictors of response that can be recognized, likely due to the differences between studies related to neuroanatomical targets and stimulation protocols assessed. In conclusion, the author indicates that DBS is a promising therapy for patients with severe resistant OCD, providing both ST and LT evidence of efficacy. Many unknowns remain, including the optimal anatomical targets, the criteria for standardized stimulation protocols, and the identification of biomarkers or factors that predict outcomes and allow treatment individualization. Larger more robust studies are needed to evaluate this technology to better determine the unknowns presented in this review.

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.

In a 2021 (updated 2022) report, Hayes evaluated the use of deep brain stimulation (DBS) for the treatment of refractory obsessive-compulsive disorder. An overall low-quality body of evidence suggests that the effectiveness of DBS for treatment of highly refractory OCD remains uncertain despite several double-blind, crossover trials. Despite its favorable results, the sample sizes are very low; there were no studies that compared DBS to an alternate intervention; treatment planning was highly individualized with trial phases with included considerable heterogeneity. Additional studies that are



sufficiently driven with consistent reporting of non-primary outcome measures and long-term follow-up would help to inform whether DBS offers any sustained benefit to individuals with refractory OCD. Specifically, studies comparing DBS with clinical alternatives in a non-crossover design would help to inform whether DBS is indeed a viable treatment option. (Hamani 2014 included in this report).

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 participants 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 participants 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.

## **Clinical Practice Guidelines**

### ***National Institute for Health and Care Excellence (NICE)***

- Evidence on the safety and efficacy of deep brain stimulation for chronic, severe, treatment-resistant obsessive-compulsive disorder (OCD) in adults is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research.
- Patient selection should be done by a multidisciplinary team experienced in managing OCD. It should include experts in psychiatry, neuropsychiatry, clinical psychology, neurology, neurosurgery and deep brain stimulation.
- The procedure should only be done in centers with expertise in deep brain stimulation and experience in managing OCD.
- Further research should primarily be randomized controlled trials. It should clearly define the area of the brain that should be targeted in this procedure. It should also describe details of patient selection, comorbidities, and use of adjunctive therapies. Outcomes should include reduction in OCD symptoms, improvement in quality of life and any neuropsychiatric and cognitive effect. (NICE April 28, 2021)

## 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): <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnm.cfm>. (Accessed October 2, 2024)

For information on responsive cortical devices refer to the following website (use product code PFN): <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnm.cfm>. (Accessed October 2, 2024)

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## Policy History/Revision Information

Date	Summary of Changes
05/01/2025	<p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"><li>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 and responsive cortical stimulation</i></li></ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"><li>Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, <i>FDA</i>, and <i>References</i> sections to reflect the most current information</li><li>Archived previous policy version CS030OH.B</li></ul>

## Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state (Ohio Administrative Code [OAC]) or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state (OAC) or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state (OAC) or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state (OAC) 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 uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) for substance use, in administering health benefits. If InterQual® does not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and/or Utilization Review Guidelines that have been approved by the Ohio Department for Medicaid Services. The UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and Utilization Review Guidelines 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.