

# Deep Brain and Cortical Stimulation

**Policy Number:** SURGERY 090.30

**Effective Date:** February 1, 2024

[➔ Instructions for Use](#)

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## Related Policy

- [Vagus and External Trigeminal Nerve Stimulation](#)

## Coverage Rationale

[➔ See Benefit Considerations](#)

**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, 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 for all other indications
- Responsive cortical stimulation for treating all other indications

## Documentation Requirements

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 documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

CPT/HCPCS Codes*	Required Clinical Information
<b>Deep Brain and Cortical Stimulation</b>	
61863 61864 61867 61868 61885 61886 L8679 L8680 L8682 L8685 L8686 L8687 L8688	Medical notes documenting the following, when applicable: <ul style="list-style-type: none"> <li>• Diagnosis</li> <li>• Specify specific procedure</li> <li>• History of the medical condition(s) requiring treatment or surgical intervention, including condition interference with activity of daily living</li> <li>• Documentation of signs and symptoms; including onset, duration, and frequency, including seizures history including number of seizures per month</li> <li>• Physical exam</li> <li>• Relevant medical history, including:               <ul style="list-style-type: none"> <li>○ Medical co-morbidities</li> <li>○ Psychiatric co-morbidities</li> </ul> </li> <li>• Treatments tried, failed, or contraindicated; include the dates and reason for discontinuation</li> <li>• Current medications used to treat condition, include start date</li> <li>• Relevant surgical history, including previous movement disorder surgery and dates</li> <li>• Reports of all recent imaging studies and applicable diagnostics, including:               <ul style="list-style-type: none"> <li>○ Results of imaging for skeletal deformities and cervical myelopathy</li> <li>○ Results of brain MRI</li> <li>○ Results of video electroencephalographic (EEG) monitoring</li> <li>○ Results of levodopa challenge</li> <li>○ Results of Yale-Brown Obsessive-Compulsive Scale (Y-BOCS)</li> </ul> </li> <li>• Physician treatment plan, including:               <ul style="list-style-type: none"> <li>○ Member understanding of surgical risk, complications and need for follow-up</li> <li>○ Planned placement of electrodes for preoperative mapping</li> </ul> </li> </ul>

\*For code descriptions, refer to 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 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

CPT Code	Description
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
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

*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, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, 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.

## 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)*

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 patient 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 experiences 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 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.

## 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.

## 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 September 6, 2023)

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](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_template.cfm?id=p150031). (Accessed September 6, 2023)

### 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 Web site for more information: [https://www.accessdata.fda.gov/cdrh\\_docs/pdf5/H050003a.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf5/H050003a.pdf). (Accessed September 6, 2023)

## 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 September 6, 2023)

## 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

The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed, and approved by UnitedHealthcare Medical Technology Assessment Committee. [2024T0321GG]

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## Policy History/Revision Information

Date	Summary of Changes
02/01/2024	<p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>Revised list of proven and medically necessary indications; replaced “refractory epilepsy” with “refractory epilepsy <i>for a partial or focal seizure disorder</i>”</li> </ul> <p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>Updated list of applicable CPT codes to reflect annual edits; added 61889 and 61891</li> </ul> <p><b>Benefit Considerations (new to policy)</b></p> <ul style="list-style-type: none"> <li>Added language to indicate: <ul style="list-style-type: none"> <li>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</li> <li>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</li> <li>Consult the member specific benefit plan document for details</li> </ul> </li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information</li> <li>Archived previous policy version SURGERY 090.29</li> </ul>

## Instructions for Use

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford 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 Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members.

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