Deep Brain and Cortical Stimulation (for Nebraska Only)

Policy Number: CS030NE.M
Effective Date: August 1, 2022

Instructions for Use

Table of Contents Page

Related Policy

- Vagus and External Trigeminal Nerve Stimulation (for Nebraska Only)

Application

This Medical Policy only applies to the state of Nebraska.

Coverage Rationale

Deep Brain Stimulation

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 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 not listed above.
- 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

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. 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.

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 ± 8.0 months for the ST studies and 63.7 ± 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 (≥ 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, seven 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 guidelines development methodology of the American Association of Neurological Surgeons/Congress of Neurological Surgeons Joint Guidelines Committee. Of the seven studies, one class I and two 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 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 December 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). Refer to the following website for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_template.cfm?id=p150031. (Accessed December 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). Refer to the following website for more information: https://www.accessdata.fda.gov/cdrh_docs/pdf5/H050003a.pdf.
(Accessed December 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

Refer to the following website for more information:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P100026. (Accessed December 28, 2021)

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

American Psychiatric Association (APA). Guideline Watch (March 2013): Practice Guideline for the Treatment of Patients with Obsessive-Compulsive Disorder. Available at: http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/ocd-watch.pdf. Accessed December 28, 2021.

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Rapinesi C, Kotzalidis GD, Ferracuti S, et al. Brain stimulation in obsessive-compulsive disorder (OCD): a systematic review. Curr Neuropharmacol. 2019;17(8):787-807.

Roper JA, Kang N, Ben J, et al. Deep brain stimulation improves gait velocity in Parkinson's disease: a systematic review and meta-analysis. J Neurol. 2016 Jun;263(6):1195-203.

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Policy History/Revision Information

Date	Summary of Changes
08/01/2022	**Coverage Rationale** • Updated language to clarify responsive cortical stimulation is proven and medically necessary for treating *refractory* partial or focal seizure disorder **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version CS030NE.L

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.