Introduction

Deep brain stimulation (DBS) can be used to treat essential tremor, Parkinson disease, and a movement disorder called dystonia. Deep brain stimulation is used when drugs aren’t able to control symptoms. It works by blocking electrical signals in specific areas of the brain that control movement. Surgery is needed to place a thin metal rod, called an electrode, in the brain. (When severe movement affects both sides of the body, an electrode may be implanted on each side of the brain.) The electrode is attached to a small device called a neurostimulator, which is placed under the skin below the collar bone. Batteries power the neurostimulator to send electrical signals to the electrode. This policy describes when deep brain stimulation may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
<table>
<thead>
<tr>
<th>Application</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| DBS of the thalamus | Deep brain stimulation (DBS) of the thalamus may be considered medically necessary for either of the following:  
  • Unilateral treatment of disabling, medically unresponsive tremor* due to:  
    o Parkinson’s disease; OR  
    o Essential Tremor  
  OR  
  • Bilateral treatment of disabling, medically unresponsive tremor* in both upper limbs due to:  
    o Parkinson’s disease; OR  
    o Essential tremor  
*See Definition of Terms |

| DBS of the globus pallidus or subthalamic nucleus (unilateral or bilateral) | Unilateral or bilateral deep brain stimulation (DBS) of the globus pallidus or subthalamic nucleus may be considered medically necessary for either of the following:  
  • Parkinson’s disease with ALL of the following:  
    o A good response to levodopa; AND  
    o Motor complications not controlled by drug treatment; AND  
    o One of the following:  
      ▪ A minimum score of 30 points on the motor portion of the Unified Parkinson Disease Rating Scale (UPDRS) when the patient has been without medication for approximately 12 hours; OR  
      ▪ Parkinson’s disease for at least 4 years  
  OR  
  • Primary dystonia** with ALL of the following:  
    o Patients older than 7 years of age; AND  
    o Chronic, intractable (drug refractory) |
**Application**

Medical Necessity

**Note:** may include generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis)

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**Application**

Investigational

DBS for other disorders

Deep brain stimulation is considered investigational for:

- Other disorders, including but not limited to:
  - Multiple sclerosis
  - Post-traumatic dyskinesia
  - Tardive dyskinesia
  - Chronic cluster headaches
- Other psychiatric or neurologic diagnoses, including but not limited to:
  - Alcohol addiction
  - Alzheimer disease
  - Anorexia nervosa
  - Chronic pain
  - Depression
  - Epilepsy
  - Obsessive-compulsive disorder
  - Tourette syndrome

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**Documentation Requirements**

The patient’s medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include clinical documentation of:

- Diagnosis/condition
- History and physical examination documenting the severity of the condition
- Area planned for deep brain stimulation (thalamus, globus pallidus, or subthalamic nucleus)
- Response to levodopa
- Unified Parkinson Disease Rating Scale score
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>61850</td>
<td>Twist drill or burr hole(s) for implantation of neurostimulator or electrodes, cortical.</td>
</tr>
<tr>
<td>61860</td>
<td>Craniectomy or craniotomy for implantation of neurostimulator electrodes, cerebral, cortical</td>
</tr>
<tr>
<td>61863</td>
<td>Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; first array</td>
</tr>
<tr>
<td>61864</td>
<td>Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; each additional array (List separately in addition to primary procedure)</td>
</tr>
<tr>
<td>61867</td>
<td>Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; first array</td>
</tr>
<tr>
<td>61868</td>
<td>Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; each additional array (List separately in addition to primary procedure)</td>
</tr>
<tr>
<td>61885</td>
<td>Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array</td>
</tr>
<tr>
<td>61886</td>
<td>Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays</td>
</tr>
</tbody>
</table>

**HCPCS**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L8680</td>
<td>Implantable neurostimulator electrode, each</td>
</tr>
<tr>
<td>L8685</td>
<td>Implantable neurostimulator pulse generator, single array, rechargeable, includes extension</td>
</tr>
<tr>
<td>L8686</td>
<td>Implantable neurostimulator pulse generator, single array non-rechargeable, includes extension</td>
</tr>
<tr>
<td>L8687</td>
<td>Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension</td>
</tr>
<tr>
<td>L8688</td>
<td>Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension</td>
</tr>
</tbody>
</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).
Related Information

Definition of Terms

Disabling, medically unresponsive tremor is defined as all of the following:

- Tremor causing significant limitation in daily activities
- Inadequate control by maximal dosage of medication for at least 3 months before implant

Contraindications to deep brain stimulation include:

- Patients who are not good surgical risks because of unstable medical problems or because of the presence of a cardiac pacemaker
- Patients who have medical conditions that require repeated magnetic resonance imaging
- Patients who have dementia that may interfere with the ability to cooperate
- Patients who have had botulinum toxin injections within the last 6 months

Evidence Review

Description

Deep brain stimulation (DBS) involves the stereotactic placement of an electrode into a central nervous system nucleus (eg, hypothalamus, thalamus, globus pallidus, subthalamic nucleus). DBS is used as an alternative to permanent neuroablative procedures for control of essential tremor and Parkinson disease. DBS is also being evaluated for the treatment of a variety of other neurologic and psychiatric disorders.
Background

Deep Brain Stimulation

Deep brain stimulation involves the stereotactic placement of an electrode into the brain (ie, hypothalamus, thalamus, globus pallidus, or subthalamic nucleus). The electrode is initially attached to a temporary transcutaneous cable for short-term stimulation to validate treatment effectiveness. Several days later, the patient returns for permanent subcutaneous surgical implantation of the cable and a radiofrequency-coupled or battery-powered programmable stimulator. The electrode is typically implanted unilaterally on the side corresponding to the most severe symptoms. However, use of bilateral stimulation using two electrode arrays has also been investigated in patients with bilateral, severe symptoms. After implantation, noninvasive programming of the neurostimulator can be adjusted to the patient’s symptoms. This feature may be important for patients with Parkinson disease (PD), whose disease may progress over time, requiring different neurostimulation parameters. Setting the optimal neurostimulation parameters may involve the balance between optimal symptom control and appearance of adverse effects of neurostimulation such as dysarthria, disequilibrium, or involuntary movements.

Essential Tremor and Tremor in PD

DBS has been investigated as an alternative to permanent neuroablative procedures, such as thalamotomy and pallidotomy. DBS has been most thoroughly investigated as an alternative to thalamotomy for unilateral control of essential tremor (ET) and tremor associated with Parkinson’s disease (PD). More recently, there has been research interest in the use of DBS of the globus pallidus or subthalamic nucleus as a treatment of other parkinsonian symptoms, such as rigidity, bradykinesia, and akinesia. Another common morbidity associated with PD is the occurrence of motor fluctuations, referred to as an “on and off” phenomena, related to the maximum effectiveness of drugs (ie, “on” state) and the nadir response during drug troughs (ie, “off” state). In addition, levodopa, the most commonly used anti-Parkinson drug, may be associated with disabling drug-induced dyskinesias. Therefore, the optimal pharmacologic treatment of PD may involve a balance between optimal effects on PD symptoms versus the appearance of drug-induced dyskinesias. The effect of DBS on both PD symptoms and drug-induced dyskinesias has also been studied.
Primary and Secondary Dystonia

DBS has also been investigated in patients with primary and secondary dystonia, defined as a neurologic movement disorder characterized by involuntary muscle contractions, which force certain parts of the body into abnormal, contorted, and painful movements or postures. Dystonia can be classified according to age of onset, bodily distribution of symptoms, and cause. Age of onset can occur during childhood or during adulthood. Dystonia can affect certain portions of the body (focal dystonia and multifocal dystonia) or the entire body (generalized dystonia). Torticollis is an example of a focal dystonia. Primary dystonia is defined when dystonia is the only symptom unassociated with other pathology. Secondary dystonia is a dystonia brought on by an inciting event, such as a stroke, trauma, or drugs. Tardive dystonia is a form of drug-induced secondary dystonia. Treatment options for dystonia include oral or injectable medications (ie, botulinum toxin) and destructive surgical or neurosurgical interventions (ie, thalamotomies or pallidotomies) when conservative therapies fail.

Summary of Evidence

For individuals who have essential tremor (ET) or tremor in PD who receive DBS of the thalamus, the evidence includes a systematic review and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The systematic review (a TEC Assessment) concluded that there was sufficient evidence that DBS of the thalamus results in clinically significant tremor suppression and that outcomes after DBS were at least as good as thalamotomy. Subsequent studies reporting long-term follow-up have supported the conclusions of the TEC Assessment and found that tremors were effectively controlled five to six years after DBS. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have symptoms (eg, speech, motor fluctuations) associated with PD (advanced or >4 years in duration with early motor symptoms) who receive DBS of the globus pallidus interna (GPI) or subthalamic nucleus (STN), the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. One of the systematic reviews (a TEC Assessment) concluded that studies evaluating DBS of the GPI or STN have consistently demonstrated clinically significant improvements in outcomes (eg, neurologic function). Other systematic reviews have also found significantly better outcomes after DBS than after a control intervention. An RCT in patients with levodopa-responsive PD of at least four years in duration and uncontrolled motor symptoms found that quality of life at two years was significantly higher when DBS was provided in addition to medical therapy. Meta-analyses of RCTs comparing DBS of the GPI with DBS of the
STN have reported mixed findings and have not shown that one type of stimulation is clearly superior to the other. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have primary dystonia who receive DBS of the GPi or STN, the evidence includes systematic reviews, RCTs, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A pooled analysis of 24 studies, mainly uncontrolled, found improvements in motor scores and disability scores after 6 months and at last follow-up (mean, 32 months). Both double-blind RCTs found that severity scores improved more after active than after sham stimulation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have tardive dyskinesia or tardive dystonia who receive DBS, the evidence includes an RCT and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Few studies were identified and they had small sample sizes (range, 9-19 patients). The RCT did not report statistically significant improvement in the dystonia severity outcomes or the secondary outcomes related to disability and QOL but may have been under-powered. Additional studies, especially RCTs or other controlled studies, are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have epilepsy who receive DBS, the evidence includes systematic reviews, RCTs, and many observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Two RCTs with more than 15 patients were identified. The larger RCT evaluated anterior thalamic nucleus DBS and reported that DBS had a positive impact on seizure frequency during some parts of the blinded trial phase but not others, and a substantial number of adverse events (in >30% of patients). There were no differences between groups in 50% responder rates, LSSS, or QOLIE-31 scores. A seven year open-label follow-up of the RCT included 66% of implanted patients; reasons for missing data were primarily related to adverse events or dissatisfaction with the device. Reduction in seizure frequency continued to improve during follow-up among the patients who continued follow-up. The smaller RCT (N=16) showed a benefit with DBS. Many small observational studies reported fewer seizures compared with baseline, however, without control groups, interpretation of these results is limited. Additional trials are required to determine the impact of DBS on patient outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have Tourette syndrome (TS) who receive DBS, the evidence includes observational studies, RCTs, and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Two RCTs with 15 or more
patients have been reported. One RCT found differences in severity of TS for active vs sham at three months while the other RCT did not. Neither study demonstrated improvements in comorbid symptoms of OCD or depression. Both studies reported high rates of serious adverse events. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have cluster headaches or facial pain who receive DBS, the evidence includes a randomized crossover study and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. In the randomized study, the between-group difference in response rates did not differ significantly between active and sham stimulation phases. Additional RCTs or controlled studies are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have treatment-resistant depression who receive DBS, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The only double-blind, parallel-group RCT in patients with depression did not find that DBS significantly increased the response rate compared with sham; two other RCTs were stopped due to futility. A crossover controlled trial randomized patients to active or to sham stimulation after a year of open-label stimulation. There was a greater reduction in symptom scores after active stimulation, but only in patients who were responders in the open-label phase; these findings may not be generalizable. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have obsessive-compulsive disorder (OCD) who receive DBS, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Among the RCTs on DBS for OCD, only one has reported the outcome of greatest clinical interest (therapeutic response rate), and that trial did not find a statistically significant benefit for DBS compared with sham treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have multiple sclerosis (MS) who receive DBS, the evidence includes an RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. One RCT with ten MS patients is insufficient evidence on which to draw conclusions about the impact of DBS in this population. Additional trials are required. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have anorexia nervosa, alcohol addiction, Alzheimer disease, Huntington disease, or chronic pain who receive DBS, the evidence includes case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. RCTs are
needed to evaluate the efficacy of DBS for these conditions. The evidence is insufficient to determine the effects of the technology on health outcomes.

## Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

### Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02480803</td>
<td>Treatment in Advanced Parkinson’s Disease: Continuous Intrajejunal Levodopa INfusion VERSus Deep Brain STimulation</td>
<td>66</td>
<td>Dec 2023</td>
</tr>
<tr>
<td>NCT01329133</td>
<td>Deep Brain Stimulation and Obsessive-Compulsive Disorder (STOC2)</td>
<td>31</td>
<td>Mar 2020</td>
</tr>
<tr>
<td>NCT02076698</td>
<td>Clinical and Medico-economical Assessment of Deep Brain Stimulation of the Anterior Nucleus of the Thalamus for the Treatment of Pharmacoresistant Partial Epilepsy</td>
<td>62</td>
<td>Dec 2019</td>
</tr>
<tr>
<td>NCT01973478</td>
<td>Deep Brain Stimulation in Patients With Chronic Treatment Resistant Depression</td>
<td>40</td>
<td>Jan 2020 (suspended)</td>
</tr>
<tr>
<td>NCT02535884*</td>
<td>Deep Brain Stimulation (DBS) of the Globus Pallidus (GP) in Huntington’s Disease (HD) (HD-DBS)</td>
<td>50</td>
<td>Oct 2020</td>
</tr>
<tr>
<td>NCT02937688*</td>
<td>Deep Brain Stimulation (DBS) for Parkinson’s Disease International Study (REACH-PD)</td>
<td>264</td>
<td>Apr 2021</td>
</tr>
<tr>
<td>NCT00354133</td>
<td>The Effect of Deep Brain Stimulation of the Subthalamic Nucleus (STN-DBS) on Quality of Life in Comparison to Best Medical Treatment in Patients With Complicated Parkinson’s Disease and Preserved Psychosocial Competence (EARLYSTIM-study)</td>
<td>251</td>
<td>Mar 2022</td>
</tr>
<tr>
<td>NCT01839396*</td>
<td>Implantable Neurostimulator for the Treatment of Parkinson’s Disease (INTREPID)</td>
<td>311</td>
<td>Aug 2023</td>
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<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01801319</td>
<td>A Clinical Evaluation of Subcallosal Cingulate Gyrus Deep Brain Stimulation for Treatment-Resistant Depression</td>
<td>40</td>
<td>Dec 2017 (ongoing)</td>
</tr>
<tr>
<td>NCT No.</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
</tr>
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<tr>
<td>NCT00640133</td>
<td>Effectiveness of Deep Brain Stimulation for Treating People with Treatment Resistant Obsessive-Compulsive Disorder</td>
<td>27</td>
<td>Feb 2018</td>
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<tr>
<td>NCT01221948</td>
<td>VANTAGE STUDY Vercise™ Implantable Stimulator for Treating Parkinson’s Disease</td>
<td>53</td>
<td>Jun 2018</td>
</tr>
<tr>
<td>NCT02583074</td>
<td>Subthalamic Deep Brain Stimulation in Patients With Medication-Refractory Primary Cranial-Cervical Dystonia: A Randomised, Sham-controlled Trial</td>
<td>40</td>
<td>Dec 2018</td>
</tr>
</tbody>
</table>

NCT: national clinical trial

a Denotes industry-sponsored or cosponsored trial

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 2 academic medical centers and 2 physician specialty societies while this policy was under review in 2014. Input supported the use of bilateral deep brain stimulation in patients with medically unresponsive tremor in both limbs.

Practice Guidelines and Position Statements

European Academy of Neurology

The European Academy of Neurology (2016) published guidelines on neuromodulation in management of chronic pain. Due to “very low” quality of evidence, the Academy could not recommend deep brain stimulation (DBS) for treatment of neuropathic pain.
American Academy of Neurology

Essential Tremor

The American Academy of Neurology (AAN) (2011) updated its guidelines on the treatment of essential tremor (ET). This update did not change the conclusions and recommendations of the AAN (2005) practice parameters on DBS for ET. The guidelines stated that bilateral DBS of the thalamic nucleus may be used to treat medically refractory limb tremor in both upper limbs (level C, possibly effective), but that there were insufficient data regarding the risk/benefit ratio of bilateral vs unilateral DBS in the treatment of limb tremor. There was insufficient evidence to make recommendations on the use of thalamic DBS for head or voice tremor (level U, treatment is unproven).

Parkinson Disease

The guidelines from the AAN (2006) on the treatment of Parkinson disease (PD) with motor fluctuations and dyskinesia found that, although criteria are evolving, patients with PD considered candidates for DBS include those who are levodopa-responsive, nondemented, and neuropsychiatrically intact patients who have intractable motor fluctuations, dyskinesia, or tremor. The AAN concluded that DBS of the subthalamic nucleus (STN) may be considered a treatment option in PD patients to improve motor function and to reduce motor fluctuations, dyskinesia, and medication usage (Level C, possibly effective), but found evidence insufficient to make any recommendations about the effectiveness of DBS of the globus pallidus or the ventral intermediate nucleus of the thalamus in reducing motor complications or medication usage, or in improving motor function in PD patients.

The guidelines from AAN (2010) on the treatment of nonmotor symptoms of PD found insufficient evidence for the treatment of urinary incontinence with DBS of the STN. The AAN found that DBS of the STN possibly improves sleep quality in patients with advanced PD. However, none of the studies performed DBS to treat insomnia as a primary symptom, and DBS of the STN is not currently used to treat sleep disorders.

Tardive Syndromes

The guidelines from the AAN (2013) on the treatment of tardive syndromes were updated in 2018. The latest guidelines state that “pallidal DBS possibly improves tardive dyskinesia and might be considered as a treatment for intractable tardive dyskinesia (Level C, which indicates
that the treatment is possibly effective, based on \( \geq 1 \) class II study and consistent with \( \geq 2 \) class III studies).

**European Society for the Study of Tourette Syndrome**

The European Society for the Study of Tourette Syndrome (2011) published guidelines on DBS.\(^{69}\) The guidelines stated that DBS for Tourette syndrome is still in its infancy and that there are no randomized controlled trials that have included a sufficiently large number of patients. The Society suggested that DBS should only be used in adult, treatment-resistant, and severely affected patients, and highly recommended that DBS be performed in the context of controlled and double-blind trials including larger and carefully characterized groups of patients.

**Canadian Network for Mood and Anxiety Treatments**

The Canadian Network for Mood and Anxiety Treatments’ (2009) clinical guidelines for management of major depressive disorder in adults found emerging evidence to support DBS as an experimental intervention for patients with treatment-refractory depression.\(^{70}\) There was no consensus on the most effective target brain region for implantation, although three regions have been explored (subcallosal cingulated gyrus, the nucleus accumbens, and the ventral caudate/ventral striatum region).

**American Society for Stereotactic and Functional Neurosurgery et al**

The American Society for Stereotactic and Functional Neurosurgery and the Congress of Neurological Surgeons (2014) published a joint systematic review and guidelines on DBS for obsessive-compulsive disorder.\(^{58}\) The document concluded that there was a single level I study supporting the use of bilateral STN DBS for medically refractory obsessive-compulsive disorder and a single level II study supporting bilateral nucleus accumbens DBS for medically refractory obsessive-compulsive disorder. It also concluded that the evidence on unilateral DBS was insufficient.
National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (NICE) has published guidance documents on DBS, as discussed in the following subsections.

**Tremor and Dystonia**

The NICE (2006) made the same statements about use of DBS for treatment of both tremor and dystonia.\(^1\) Unilateral and bilateral stimulation of structures responsible for modifying movements, such as the thalamus, globus pallidus, and the STN, which interact functionally with the substantia nigra, are included in both guidance statements. The guidance stated: “Current evidence on the safety and efficacy of deep brain stimulation for tremor and dystonia (excluding Parkinson’s disease) appears adequate to support the use of this procedure.”

**Refractory Chronic Pain Syndromes (Excluding Headache)**

The guidance from NICE (2011) indicated there is evidence that DBS for refractory chronic pain (excluding headache) is associated with serious risks.\(^2\) However, the procedure is “efficacious in some patients refractory to other treatments.” Patients should be informed that DBS may not control their chronic pain symptoms and that possible risks associated with this procedure include the small risk of death.

**Intractable Trigeminal Autonomic Cephalgias**

The guidance from NICE (2011) indicated that the evidence on the efficacy of DBS for intractable trigeminal autonomic cephalalgias (eg, cluster headaches) was “limited and inconsistent, and the evidence on safety shows that there were serious but well-known adverse effects.”\(^3\)

**Refractory Epilepsy**

The guidance from NICE (2012) indicated that the evidence on the efficacy of DBS for refractory epilepsy was limited in both quantity and quality: “The evidence on safety showed that there are serious but well-known adverse effects.”\(^4\)
Parkinson Disease

The NICE (2003) stated that the evidence on the safety and efficacy of DBS for treatment of PD “appears adequate to support the use of the procedure.” The guidance noted that DBS should only be offered when PD is refractory to best medical treatment.

Medicare National Coverage

Effective for services furnished in after April 2003, Medicare covers unilateral or bilateral thalamic ventralis intermedius nucleus DBS for the treatment of ET and/or parkinsonian tremor and unilateral or bilateral STN or globus pallidus interna DBS for the treatment of PD when the following conditions are met:

- Devices must be approved by the Food and Drug Administration (FDA) for “DBS or devices used in accordance with FDA-approved protocols governing Category B Investigational Device Exemption (IDE) DBS clinical trials.”

- For thalamic ventralis intermedius nucleus DBS, patients must meet ALL of the following criteria:
  - Diagnosis of ET based on postural or kinetic tremors of hand(s) without other neurologic signs, or diagnosis of idiopathic PD (presence of at least 2 cardinal PD features [tremor, rigidity or bradykinesia]) which is of a tremor-dominant form.
  - Marked disabling tremor of at least level 3 or 4 on the Fahn-Tolosa-Marin Clinical Tremor Rating Scale (or equivalent scale) in the extremity intended for treatment, causing significant limitation in daily activities despite optimal medical therapy.
  - Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.

- For STN or globus pallidus interna DBS, patients must meet ALL of the following criteria:
  - Diagnosis of PD based on the presence of at least 2 cardinal PD features (tremor, rigidity or bradykinesia).
  - Advanced idiopathic PD as determined by the use of Hoehn and Yahr stage or Unified Parkinson's Disease Rating Scale (UPDRS) part III motor subscale.
  - L-dopa responsive with clearly defined "on" periods.
○ “Persistent disabling Parkinson’s symptoms or drug side effects (eg, dyskinesias, motor fluctuations, or disabling “off” periods) despite optimal medical therapy.

○ “Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings”

DBS is not covered for ET or PD patients with ANY of the following:

- “Non-idiopathic Parkinson’s disease or ‘Parkinson’s Plus’ syndromes.
- Cognitive impairment, dementia or depression, which would be worsened by or would interfere with the patient’s ability to benefit from DBS.
- Current psychosis, alcohol abuse or other drug abuse.”

Structural lesions such as basal ganglionic stroke, tumor or vascular malformation as etiology of the movement disorder.

Previous movement disorder surgery within the affected basal ganglion.

Significant medical, surgical, neurologic or orthopedic co-morbidities contraindicating DBS surgery or stimulation.”

Regulatory Status

In 1997, the Activa® Tremor Control System (Medtronic) was cleared for marketing by the U.S. Food and Drug Administration (FDA) for DBS. The Activa® Tremor Control System consists of an implantable neurostimulator, a deep brain stimulator lead, an extension that connects the lead to the power source, a console programmer, a software cartridge to set electrical parameters for stimulation, and a patient control magnet, which allows the patient to turn the neurostimulator on and off, or change between high and low settings.

The original FDA-labeled indications for Activa® were limited to unilateral implantation of the device for the treatment of tremor, but, in 2002, the FDA-labeled indications were expanded to include bilateral implantation as a treatment to decrease the symptoms of advanced PD not controlled by medication. In 2003, the labeled indications were further expanded to include “…unilateral or bilateral stimulation of the internal globus pallidus or subthalamic nucleus to aid in the management of chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis) in patients seven years of age or above.” This latter indication was cleared for marketing by the FDA through the humanitarian device exemption process. In 2017, the indications for PD were
modified to include “adjunctive therapy in reducing some of the symptoms in individuals with levodopa-responsive Parkinson’s Disease of at least 4 years’ duration that are not adequately controlled with medication.”

In 2009, the Reclaim® device (Medtronic), a DBS device, was cleared for marketing by the FDA through the humanitarian device exemption process for the treatment of severe obsessive-compulsive disorder.

In 2014, the Brio Neurostimulation System (now called Infinity; St. Jude Medical Neuromodulation) was cleared for marketing by the FDA for the treatment of Parkinsonian tremor.

In 2016, the St. Jude Medical’s Infinity DBS device with directional leads was approved by the FDA. The directional leads enable the clinician to “steer” current to different parts of the brain. This tailored treatment reduces side effects. The Infinity system can be linked to Apple’s iPod Touch and iPad Mini.

In 2017, a second system with directional leads, the Vercise Deep Brain Stimulation System (Boston Scientific), was approved by the FDA. This system is to be used as an adjunctive therapy from reducing motor symptoms of moderate-to-advanced levodopa-responsive PD inadequately controlled with medication alone.

In 2018, the FDA approved the Medtronic DBS System for Epilepsy (Medtronic, Inc) through the Premarket Approval process. The pivotal study was the Stimulation of the Anterior Nucleus of the Thalamus for Epilepsy. The intended use is bilateral stimulation of the anterior nucleus of the thalamus as an adjunctive therapy for reducing the frequency of seizures in individuals 18 years of age or older diagnosed with epilepsy characterized by partial-onset seizures, with or without secondary generalization, that are refractory to three or more antiepileptic medications.

FDA product code: MHY

References


## History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/25/98</td>
<td>Add to Surgery Section - New Policy</td>
</tr>
<tr>
<td>01/07/99</td>
<td>Coding Update - 1999 CPT Coding Release.</td>
</tr>
<tr>
<td>05/09/00</td>
<td>Replace Policy - Policy reviewed; new information added on bilateral stimulation and different sites of stimulation; underlying policy statement unchanged.</td>
</tr>
<tr>
<td>06/02/00</td>
<td>Replace Policy - Added cross-references to other stimulation policies.</td>
</tr>
<tr>
<td>04/09/02</td>
<td>Replace Policy - Policy updated based on TEC Assessment; policy statement revised to include a broader range of patients w/Parkinson’s disease.</td>
</tr>
<tr>
<td>10/16/03</td>
<td>Replace Policy - Policy revised with focus on new FDA-labeled indication for primary refractory dystonia. Rest of policy statement is unchanged.</td>
</tr>
<tr>
<td>01/01/04</td>
<td>Replace Policy - CPT code updates only.</td>
</tr>
<tr>
<td>05/11/04</td>
<td>Replace Policy - Policy reviewed, additional CPT codes added. No change to policy statement.</td>
</tr>
<tr>
<td>06/14/05</td>
<td>Replace Policy - Policy revised with information and policy statement added on deep brain stimulation for cluster headaches. The previous policy statements are unchanged.</td>
</tr>
<tr>
<td>02/06/06</td>
<td>Codes updated - No other changes.</td>
</tr>
<tr>
<td>06/16/06</td>
<td>Replace Policy - Policy revised with literature review; references added; policy statements are unchanged. Scope and Disclaimer language updated.</td>
</tr>
<tr>
<td>01/26/07</td>
<td>Codes Updated - No other changes.</td>
</tr>
<tr>
<td>06/15/07</td>
<td>Cross Reference Update - No other changes.</td>
</tr>
<tr>
<td>11/13/07</td>
<td>Replace Policy - Policy revised with literature review; references added. Policy statement updated with treatment of other psychiatric or neurologic disorders is considered investigational.</td>
</tr>
<tr>
<td>12/11/07</td>
<td>Cross Reference Updated - No other changes.</td>
</tr>
<tr>
<td>04/08/08</td>
<td>Codes Updated - Added 61860, no other changes</td>
</tr>
<tr>
<td>12/16/08</td>
<td>Replace Policy - Policy statement clarified to state that score of 30 points must be within the Motor section of the UPDRS.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
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<tr>
<td>05/12/09</td>
<td>Replace Policy - Policy updated with literature search, no change to the policy statement. References added.</td>
</tr>
<tr>
<td>04/13/10</td>
<td>Cross Reference Update - No other changes.</td>
</tr>
<tr>
<td>06/13/11</td>
<td>Replace Policy - Policy updated with literature review; references 27-31 added. No change in policy statements.</td>
</tr>
<tr>
<td>04/17/12</td>
<td>Related Policies updated: 7.01.546 added to replace 7.01.25 which has been deleted.</td>
</tr>
<tr>
<td>08/20/12</td>
<td>Replace policy. Rationale section revised based on literature review through April 2012. References 23-24, 31, 37-38, 44-46 added, others renumbered or removed. Policy statements unchanged.</td>
</tr>
<tr>
<td>08/27/12</td>
<td>Update Related Policy – 7.01.20 is added. Update Coding Section – ICD-10 effective dates are now 10/01/2014.</td>
</tr>
<tr>
<td>10/17/12</td>
<td>Update Related Policies – Add 6.01.54.</td>
</tr>
<tr>
<td>10/14/13</td>
<td>Replace policy. Policy updated with literature review through May 20, 2013; reference 20 added; anorexia nervosa, alcohol addiction, and chronic pain added as investigational.</td>
</tr>
<tr>
<td>12/08/14</td>
<td>Annual Review. Policy updated with literature review through June 11, 2014; clinical input reviewed; references 32, 41-43, and 52 added; bilateral stimulation of the thalamus may be medically necessary for bilateral tremor. ICD-9 and ICD-10 diagnosis and procedure codes removed; these are not utilized in adjudication of the policy.</td>
</tr>
<tr>
<td>01/26/15</td>
<td>Update Related Policies. Add 7.01.143.</td>
</tr>
<tr>
<td>07/01/16</td>
<td>Annual Review, approved June 14, 2016. Clarified that bilateral stimulation may be considered medically necessary for tremor in both upper limbs due to essential tremor or Parkinson disease. Policy updated with literature review through February 11, 2016. References 7, 10-11, 18, 22-26, 28, 33-34, and 36-38 added.</td>
</tr>
<tr>
<td>07/01/17</td>
<td>Annual Review, approved June 6, 2017. Policy moved into new format. Policy updated with literature review through February 23, 2017. References 10, 13-16, 18, 36, and 42 added. In medically necessary statement on unilateral or bilateral deep brain stimulation of the globus pallidus or subthalamic nucleus, “OR Parkinson disease for at least 4 years” added to medically necessary criteria for use in Parkinson disease.</td>
</tr>
<tr>
<td>08/25/17</td>
<td>Coding update, removed CPT codes 95970, 95971, 95978, and 95979.</td>
</tr>
<tr>
<td>01/01/18</td>
<td>Coding update, removed CPT code 0169T as it was terminated 1/1/17.</td>
</tr>
<tr>
<td>03/01/19</td>
<td>Minor update, added Documentation Requirements section.</td>
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</table>
### Date

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<tbody>
<tr>
<td>07/01/19</td>
<td>Annual Review, approved June 4, 2019. Policy updated with literature review through February 2019; references added. Policy statements unchanged.</td>
</tr>
</tbody>
</table>

**Disclaimer.** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2019 Premera All Rights Reserved.

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  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
• Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

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Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW, Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7367 (TDD) Complaint forms are available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services, 200 Independence Avenue SW, Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7367 (TDD) Complaint forms are available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

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This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

Avi sila a gen Enfòmasyon Enpòtan ladann. Avi sila a kapab genyen enfòmasyon enpòtan konsènplant apan kasej yon osa konsej kouveti asirans lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou tran kék aksyon avan séten at dat limit pou ou ka tek kouveti asirans sante w la osa pou yo ka ede w avèk depans yo. Se dwa w pou resevwa enfòmasyon sa a ak asistans nan lang ou pa aile a, san ou pa gen pou pee moy sa. Rate nan 800-722-1471 (TTY: 800-842-5357).

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Oromoo (Cushite):

Italian (Italian):
Premera Blue Cross (TTY: 800-842-5357)