Deep brain stimulation (DBS) can be used to treat essential tremor, Parkinson disease, and the movement disorder called dystonia. DBS is used when drugs can’t control symptoms. DBS works by blocking electrical signals in specific areas of the brain that control movement. During surgery, a thin metal rod, called an electrode, is placed in the brain. When severe movement affects both sides of the body, two electrodes may be implanted, one on either side of the brain. The electrode is attached to a small device called a neurostimulator that’s placed under the skin below the collar bone. The neurostimulator is powered by batteries and sends electrical signals to the electrodes. 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.
# Policy Coverage Criteria

## Application | Medical Necessity
---|---
**Thalamus** | Deep brain stimulation of the thalamus may be considered medically necessary for:
- Parkinson’s disease
  - Unilateral or bilateral treatment and
  - Tried and failed medical treatment and disabling tremor
- Essential Tremor
  - Tried and failed medical treatment and disabling tremor

**Globus pallidus or subthalamic nucleus (unilateral or bilateral)** | Deep brain stimulation of the globus pallidus or subthalamic nucleus may be considered medically necessary for:
- **Parkinson disease** with **ALL** of the following:
  - A good response to levodopa
  - Motor complications not controlled by drug treatment
  - One of the following:
    - A minimal score of 30 points on the motor portion of the Unified Parkinson Disease Rating Scale when the patient has been without medication for approximately 12 hours
    - Parkinson disease for at least 4 years
- **Primary dystonia** with **ALL** of the following:
  - Patients aged older than 7 years
  - Chronic, intractable (drug refractory) primary dystonia
  - Including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis)

## Application | Investigational
---|---
**Other** | Deep brain stimulation is considered investigational for:
- **Other movement disorders**, including but not limited to:
  - Multiple sclerosis
  - Post-traumatic dyskinesia
  - Tardive dyskinesia
<table>
<thead>
<tr>
<th>Application</th>
<th>Investigational</th>
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<tbody>
<tr>
<td></td>
<td>• Other psychiatric or neurologic diagnoses, including but not limited to:</td>
</tr>
<tr>
<td></td>
<td>o Alcohol addiction</td>
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<td></td>
<td>o Alzheimer disease</td>
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<tr>
<td></td>
<td>o Anorexia nervosa</td>
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<td></td>
<td>o Chronic pain</td>
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<td></td>
<td>o Depression</td>
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<td></td>
<td>o Epilepsy</td>
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<td></td>
<td>o Obsessive-compulsive disorder</td>
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<tr>
<td></td>
<td>o Tourette syndrome</td>
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**Coding**

<table>
<thead>
<tr>
<th>Code</th>
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<td>CPT</td>
<td></td>
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<tr>
<td>0169T</td>
<td>Stereotactic placement of infusion catheter(s) in the brain for delivery of therapeutic agent(s), including computerized stereotactic planning and burr hole(s)(code terminated 1/1/17)</td>
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<tr>
<td>61850</td>
<td>Twist drill or burr hole(s) for implantation of neurostimulator or electrodes, cortical.</td>
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<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 (e.g., 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>
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<td>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</td>
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<td>Code</td>
<td>Description</td>
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<tr>
<td>--------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</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>
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<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>
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**HCPCS**

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<td>Implantable neurostimulator electrode, each</td>
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<td>L8685</td>
<td>Implantable neurostimulator pulse generator, single array, rechargeable, includes extension</td>
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<td>L8686</td>
<td>Implantable neurostimulator pulse generator, single array non-rechargeable, includes extension</td>
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<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 and
- Inadequately controlled 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 (MRI)

• 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

Background

Deep brain stimulation (DBS) 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 implantation of a permanent subcutaneous cable and a radiofrequency-coupled or battery-powered programmable stimulator. The electrode is typically implanted unilaterally. However, use of bilateral stimulation using 2 electrode arrays has also been investigated in patients with severe bilateral 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.

DBS has been investigated as an alternative to permanent neuroablative procedures such as thalamotomy and pallidotomy. The technique 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, or akinesia. Another common morbidity associated with PD is the occurrence of motor fluctuations, referred to as an “on and off” phenomena. This is the difference in symptoms that a patient has when the medication is maximally effective and symptoms are more controlled (“on”) and the reemergence of symptoms during drug troughs.
("off"). 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.

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. 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. 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.

DBS has been investigated in patients with chronic cluster headaches. Cluster headaches occur as episodic attacks of severe pain lasting from 30 minutes to several hours. The pain is usually unilateral and localized to the eye, temple, forehead, and side of the face. Autonomic symptoms that occur with cluster headaches include ipsilateral facial sweating, flushing, tearing, and rhinorrhea. Cluster headaches occur primarily in men and have been classified as vascular headaches that have been associated with high blood pressure, smoking, alcohol use, etc. However, the exact pathogenesis of cluster headaches is uncertain. Positron emission tomography (PET) scanning and magnetic resonance imaging (MRI) have shown the hypothalamic region may be important in the pathogenesis of cluster headaches. Alterations in hormonal/serotonergic function may also play a role. Treatment of cluster headaches includes pharmacologic interventions for acute episodes and prophylaxis, sphenopalatine ganglion (SPG) blockade, and surgical procedures such as percutaneous SPG radiofrequency rhizotomy, and gamma knife radiosurgery of the trigeminal nerve.

The role of DBS in treatment of other treatment-resistant neurologic and psychiatric disorders, particularly Tourette syndrome, epilepsy, OCD, and major depressive disorders, is also being investigated. Ablative procedures are irreversible and, though they have been refined, remain controversial treatments for intractable illness. Interest has shifted to neuromodulation through DBS of nodes or targets within neural circuits involved in these disorders. Currently, a variety of target areas are being studied.
Summary of Evidence

The evidence for deep brain stimulation (DBS) of the thalamus in individuals who have essential tremor or tremor in Parkinson disease 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 resulted in clinically significant tremor suppression and that outcomes after DBS were at least as good as thalamotomy. Subsequent studies reporting long-term follow-up supported the conclusions of the Assessment and found that tremors were effectively controlled 5 to 6 years after DBS. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome. Therefore the treatment is considered medically necessary in these situations.

The evidence for DBS of the globus pallidus or subthalamic nucleus in individuals who have symptoms (eg, speech, motor fluctuations) associated with Parkinson disease (advanced or >4 years in duration with early motor symptoms) includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. One of the systematic reviews was a TEC Assessment, which concluded that studies on DBS of the globus pallidus or subthalamic nucleus consistently demonstrated clinically significant improvements in outcomes (eg, neurologic function). Other systematic reviews also found significantly better outcomes after DBS versus a control intervention. An RCT in patients with levodopa-responsive Parkinson disease of at least 4 years in duration and uncontrolled motor symptoms found that quality of life at 2 years was significantly higher when DBS was provided in addition to medical therapy. Meta-analyses of RCTs comparing DBS of the GPi and STN have reported mixed findings and have not shown that one type of stimulation was clearly superior to the other. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome, and medical necessity is established for this indication.

The evidence for DBS of the globus pallidus or subthalamic nucleus in individuals who have primary dystonia includes systematic reviews, case series, and an RCT. 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 the last follow-up (mean, 32 months). A double-blind RCT found that severity scores improved more after active than after sham stimulation. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome, thus establishing medical necessity.
The evidence for DBS in individuals who have tardive dyskinesia or tardive dystonia includes case series, one of which included a double-blind comparison of outcomes when the device was turned on versus off. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Few studies were identified and they had small sample sizes (≤10 patients). Additional studies, especially RCTs or other controlled studies, are needed. The evidence is insufficient to determine the effects of the technology on health outcomes, therefore DBS for this indication is investigational.

The evidence for DBS in individuals who have epilepsy includes one RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. In that single RCT, DBS had a positive impact during some parts of the blinded trial phase but not others, and a substantial number of adverse events were reported. Additional trials are required to determine the impact of DBS on the net health outcome. The evidence is insufficient to determine the effects of the technology on health outcomes, and therefore this indication is considered investigational.

For individuals who have multiple sclerosis (MS) who receive DBS, the evidence includes only 1 RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The single RCT with only 10 MS patients is insufficient evidence on which to draw conclusions about the impact of DBS on health outcomes in this population. Additional trials are required, so for multiple sclerosis DBS is investigational.

The evidence for DBS in individuals who have Tourette syndrome includes crossover RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Several small (≤15 patients) crossover studies and a 2015 meta-analysis have suggested that DBS may improve outcomes in patients with Tourette syndrome. However, the optimal target for DBS is not known and additional controlled studies in larger numbers of patients are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for DBS in individuals who have cluster headaches or facial pain 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 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.

The evidence for DBS in individuals who have treatment-resistant depression or obsessive-compulsive disorder includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The only double-blind RCT
in patients with depression did not find that DBS significantly increased the response rate versus sham, and 2 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 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 obsessive-compulsive disorder, only 1 has reported the outcome of greatest clinical interest (therapeutic response rate), and that trial did not find a statistically significant benefit for DBS compared to sham treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for DBS in individuals who have anorexia nervosa, alcohol addiction, Alzheimer disease, Huntington disease, or chronic pain includes case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. RCTs are needed to evaluate the impact of DBS on health outcomes 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>
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<td>NCT02583074</td>
<td>Subthalamic Deep Brain Stimulation in Patients With Medication-Refractory Primary Cranial-Cervical Dystonia: A Randomised, Sham-controlled Trial</td>
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<td>Sep 2017</td>
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<td>NCT02480803</td>
<td>Treatment in Advanced Parkinson's Disease: Continuous Intrajejunal Levodopa INFusion VERSus Deep Brain Stimulation</td>
<td>66</td>
<td>Dec 2018</td>
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<tr>
<td>NCT02076698</td>
<td>Clinical and Medico-economical Assessment of Deep Brain Stimulation of the Anterior Nucleus of the</td>
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<td>NCT No.</td>
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<td>Thalamus for the Treatment of Pharmacoresistant Partial Epilepsy</td>
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<td>NCT01973478</td>
<td>Deep Brain Stimulation in Patients With Chronic Treatment Resistant Depression</td>
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<tr>
<td>NCT01839396</td>
<td>Implantable Neurostimulator for the Treatment of Parkinson’s Disease</td>
<td>310</td>
<td>Jul 2021</td>
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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 provide appropriate reviewers who collaborate with and make recommendations during this process, 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 through 2 Physician Specialty Societies and 2 Academic Medical Centers while this policy was under review in 2014. The 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**

In 2016, the European Academy of Neurology (EAN) published guidelines on neuromodulation in management of chronic pain.\(^4^2\) EAN’s recommendation on deep brain stimulation (DBS) for treatment of neuropathic pain was inconclusive and based on a “very low” quality of evidence.

**American Academy of Neurology**

The American Academy of Neurology (AAN) published an updated guideline on the treatment of ET (essential tremor) in 2011.\(^4^3\) There were no changes from the conclusions and
recommendations of the 2005 practice parameters regarding DBS for ET.\textsuperscript{44} 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 versus unilateral DBS in the treatment of limb tremor. There was insufficient evidence to make recommendations regarding the use of thalamic DBS for head or voice tremor (level U, treatment is unproven).

2006 Guidelines from AAN on the treatment of PD with motor fluctuations and dyskinesia found that although the criteria are evolving, patients with PD who are considered candidates for DBS include levodopa-responsive, nondemented, and neuropsychiatrically intact patients who have intractable motor fluctuations, dyskinesia, or tremor.\textsuperscript{45} AAN concluded that DBS of the subthalamic nucleus may be considered as 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 insufficient evidence 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.

2010 Guidelines from AAN on the treatment of nonmotor symptoms of PD found insufficient evidence for the treatment of urinary incontinence with DBS of the subthalamic nucleus.\textsuperscript{46} AAN found that DBS of the subthalamic nucleus 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 subthalamic nucleus is not currently used to treat sleep disorders.

2013 Guidelines from AAN on the treatment of tardive syndromes state that the available evidence, which consists of Class IV studies comprising case reports or small case series, is insufficient to support or refute pallidal DBS for tardive syndromes.\textsuperscript{47}

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

The American Society for Stereotactic and Functional Neurosurgery and the Congress of Neurological Surgeons published a systematic review and guideline on DBS for obsessive-compulsive disorder (OCD) in 2014.\textsuperscript{38} The document concluded that there is a single level I study supporting the use of bilateral STN DBS for medically refractory OCD and a single level II study supporting bilateral nucleus accumbens DBS for medically refractory OCD. It also concluded that the evidence on unilateral DBS is insufficient.
Canadian Network for Mood and Anxiety Treatments

The Canadian Network for Mood and Anxiety Treatments’ 2009 clinical guideline for management of major depressive disorder in adults states that there is emerging evidence to support DBS as an experimental intervention for patients with treatment-refractory depression. There is no consensus on the most effective target brain region for implantation, although 3 regions have been explored (subcallosal cingulated gyrus, the nucleus accumbens, and the ventral caudate/ventral striatum region).

European Society for the Study of Tourette Syndrome

The European Society for the Study of Tourette Syndrome published guidelines on DBS in 2011. The guidelines state that DBS for Tourette syndrome is still in its infancy and that there are no RCTs available that include a sufficiently large number of patients. There was general agreement among the workgroup members that DBS should only be used in adult, treatment-resistant, and severely affected patients, and it was highly recommended that DBS be performed in the context of controlled and double-blind trials including larger and carefully characterized groups of patients.

National Institute for Health and Care Excellence (NICE)

The U.K.’s National Institute for Health and Care Excellence (NICE, previously the National Institute for Clinical Excellence) has published Interventional Procedure Guidance documents on DBS.

- **Tremor and Dystonia:** In 2006, NICE made the same statement for use of DBS for treatment of tremor and dystonia. Unilateral and bilateral stimulation of structures responsible for modifying movements, such as the thalamus, globus pallidus, and the subthalamic nucleus, 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, provided that the normal arrangements are in place for consent, audit and clinical governance.”

- **Refractory Chronic Pain Syndromes (excluding headache):** 2011 guidance states that there is evidence that DBS is efficacious for refractory chronic pain (excluding headache) but it is associated with well-known risks. However, the procedure is “efficacious in some
patients” refractory to other treatments and, therefore, it may be used provided that “normal arrangements are in place for clinical governance, consent and audit.” 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:** 2011 guidance states that current evidence on the efficacy of DBS for intractable trigeminal autonomic cephalalgias (e.g., cluster headaches) is limited and inconsistent, and the evidence on safety shows that there are serious but well-known adverse effects. Therefore this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.52

- **Refractory Epilepsy:** 2012 guidance states that the evidence on the efficacy of DBS for refractory epilepsy is limited in both quantity and quality.53 The evidence on safety shows that there are serious but well-known adverse effects. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

- **Parkinson Disease:** In 2003, NICE stated that current evidence on the safety and efficacy of DBS for treatment of PD appears adequate to support the use of the procedure, provided that normal arrangements are in place for consent, audit, and clinical governance.54

**Medicare National Coverage**

Effective for services furnished on or after April 1, 2003, Medicare will cover unilateral or bilateral thalamic ventralis intermedius nucleus (VIM) deep brain stimulation (DBS) for the treatment of ET and/or Parkinsonian tremor and unilateral or bilateral subthalamic nucleus (STN) or globus pallidus interna (GPI) DBS for the treatment of PD when the following conditions are met.55

- DBS devices must be FDA-approved devices for DBS or devices used in accordance with FDA-approved protocols governing Category B Investigational Device Exemption (IDE) DBS clinical trials.

- For thalamic VIM 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 GPi 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 deep brain stimulation. 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, FDA-labeled indications were expanded to include bilateral implantation as a treatment to decrease the symptoms of advanced Parkinson disease 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 FDA through the humanitarian device exemption (HDE) process. In 2017, the indications for Parkinson disease 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 February 2009, the FDA approved DBS with the Reclaim® device (Medtronic Inc.) via the HDE process for the treatment of severe OCD.

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.

PMA FDA product code: MHY

References


### History

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<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>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</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>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>
</tbody>
</table>
### Date | Comments
--- | ---
01/26/15 | Update Related Policies. Add 7.01.143.
07/01/16 | 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.
07/01/17 | 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.
08/25/17 | Coding update, removed CPT codes 95970, 95971, 95978, and 95979.

**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). ©2017 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
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Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - 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.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
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, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at

Getting Help in Other Languages

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).

Oromo (Cushite):

Français (French):

Kreyòl ayisyen (Creole):

Deutsche (German):

Hmoob (Hmong):

Illoko (Ilocano):
Daytoy a Pakdaara ket naglaon iti Napateg nga Impomarsion. Daytoy a pakdaara mabalin nga adda ket naglaon iti napateg nga impomarsion maipanggep iti aplikasyonu weny coverage babaen iti Premera Blue Cross. Daytoy kel mabalin dagiti importante a pelta iti daytoy a pakdaara. Mabalin nga adda rumbang nga aramidenyo nga addang sakbay dagiti partikular a nalitading nga aldaow tapno mapagtalaineyado ti coverage ti salun-atyo weny tungong kadgiatan gastos. Adda karbenganyo a mangala iti daytoy nga impomarsion ken tungong ti bukodyo a pagasasao nga awan ti bayadanoy. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):

中文 (Chinese):
本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知可能有重要的日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請拔電話 800-722-1471 (TTY: 800-842-5357).
Premera Blue Cross may contain important information about your coverage or application. It is important to review the information in this notice.

Español (Spanish): Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas claves en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog): Ang Paunawa na ito ay naglabanan ng mahalagang impormasyon. Ang paunawa na ito ay maaaring mamahagi ng mga impormasyon tungkol sa iyong aplikasyon o pagakapo sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang petsa dito sa paunawa. May kapalit na iniwanin na magtakbo na nakikidulot ng pagtala ng mga impormasyon at mga hakbang sa ilang mga itinakdang hakbang.


ไทย (Thai): ประกาศนี้มีข้อยกต่ำสุด ประกาศนี้มีข้อยกต่ำสุดเกี่ยวกับการมีสิทธิ์ต่อประกันสุขภาพของคุณกับ Premera Blue Cross และมีข้อกำหนดที่เกี่ยวกับการมีสิทธิ์ต่อประกันสุขภาพของคุณที่ต้องเกี่ยวกับข้อมูลที่ ได้รับข้อมูลที่มีความซับซ้อนและข้อมูลที่มีความซับซ้อนในการประกันสุขภาพของคุณ โปรดติดต่อ โทร 800-722-1471 (TTY: 800-842-5357).

Український (Ukrainian): Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страхувального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Ває право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дзвоніть за номером телефону 800-722-1471 (TTY: 800-842-5357).