Medical Policy
Deep Brain Stimulation

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Policy Number: 473
BCBSA Reference Number: 7.01.63
NCD/LCD: National Coverage Determination (NCD) for Deep Brain Stimulation for Essential Tremor and Parkinson Disease (160.24)

Related Policies
- Spinal Cord Stimulation, #472
- Responsive Neurostimulation for the Treatment of Refractory Partial Epilepsy, #716

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Unilateral deep brain stimulation of the thalamus may be MEDICALLY NECESSARY in patients with disabling, medically unresponsive tremor due to essential tremor or Parkinson disease.

Bilateral deep brain stimulation of the thalamus may be MEDICALLY NECESSARY in patients with disabling, medically unresponsive tremor in both upper limbs due to essential tremor or Parkinson disease.

Unilateral or bilateral deep brain stimulation of the globus pallidus or subthalamic nucleus may be MEDICALLY NECESSARY in the following patients:
- Those with Parkinson disease with ALL of the following:
  - A good response to levodopa, AND
  - 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, AND
  - Motor complications not controlled by pharmacologic therapy.
- Patients aged greater than 7 years with chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis).

Deep brain stimulation for other movement disorders, including but not limited to, multiple sclerosis, post-traumatic dyskinesia, and tardive dyskinesia, is INVESTIGATIONAL.

Deep brain stimulation for the treatment of chronic cluster headaches is INVESTIGATIONAL.
Deep brain stimulation for the treatment of other psychiatric or neurologic disorders, including but not limited to, Tourette syndrome, depression, obsessive-compulsive disorder, anorexia nervosa, alcohol addiction, chronic pain and epilepsy is INVESTIGATIONAL.

Medicare HMO BlueSM and Medicare PPO BlueSM Members

BCBSMA covers unilateral or bilateral thalamic ventralis intermedius nucleus (VIM) deep brain stimulation (DBS) for the treatment of essential tremor (ET) and/or Parkinsonian tremor and unilateral or bilateral subthalamic nucleus (STN) or globus pallidus interna (GPI) DBS for the treatment of Parkinson's disease (PD) subject to the following conditions, for Medicare HMO Blue and Medicare PPO Blue members in accordance with CMS NCD:

- Medicare will only consider DBS devices to be reasonable and necessary if they are Food and Drug Administration (FDA) approved devices for DBS or devices used in accordance with FDA approved protocols governing Category B Investigational Device Exemption (IDE) DBS clinical trials.
- Thalamic VIM DBS:
  - 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.
- STN or GPI DBS:
  - 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 (e.g., 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.

BCBSMA does not cover DBS for ET or PD patients with any of the following indications for Medicare HMO Blue and Medicare PPO Blue members in accordance with CMS NCD:

- 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.

National Coverage Determination (NCD) for Deep Brain Stimulation for Essential Tremor and Parkinson Disease (160.24)

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products.
See below for situations where prior authorization may be required or may not be required.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Commercial Managed Care (HMO and POS)</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>No</td>
</tr>
<tr>
<td>Medicare HMO BlueSM</td>
<td>No</td>
</tr>
<tr>
<td>Medicare PPO BlueSM</td>
<td>No</td>
</tr>
</tbody>
</table>

**CPT Codes / HCPCS Codes / ICD Codes**

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

**CPT Codes**

<table>
<thead>
<tr>
<th>CPT codes</th>
<th>Code Description</th>
</tr>
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<tbody>
<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</td>
</tr>
<tr>
<td>95978</td>
<td>Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, battery status, electrode selectability and polarity, impedance and patient compliance measurements), complex deep brain neurostimulator pulse generator/transmitter, with initial or subsequent programming; first hour</td>
</tr>
<tr>
<td>95979</td>
<td>Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, battery status, electrode selectability and polarity, impedance and patient compliance measurements), complex deep brain neurostimulator pulse generator/transmitter, with initial or subsequent programming; each additional 30 minutes after first hour</td>
</tr>
</tbody>
</table>
The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT codes above if medical necessity criteria are met:

### ICD-9 Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-9-CM diagnosis codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>332.0</td>
<td>Paralysis agitans</td>
</tr>
<tr>
<td>333.1</td>
<td>Essential and other specified forms of tremor</td>
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</tbody>
</table>

### ICD-10 Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10-CM Diagnosis codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>G20</td>
<td>Parkinson's disease</td>
</tr>
<tr>
<td>G21.4</td>
<td>Vascular parkinsonism</td>
</tr>
<tr>
<td>G25.0</td>
<td>Essential tremor</td>
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### Description

Deep brain stimulation (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 ET and tremor associated with 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 "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.

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 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.

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 to surgery for permanent subcutaneous 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 2 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 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.

**Summary**

Deep brain stimulation (DBS) involves the stereotactic placement of an electrode into the brain (ie, 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.

The evidence for 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.

The evidence for DBS of the globus pallidus or subthalamic nucleus in individuals who have symptoms (eg, speech, motor fluctuations) associated with advanced Parkinson disease 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. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for DBS of the globus pallidus or subthalamic nucleus in individuals who have primary dystonia includes RCTs and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Double-blind, sham-controlled studies generally found significantly better outcomes with active stimulation. The treatment was associated with adverse events, the most common of which was nonserious dysarthria. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for DBS in individuals who have tardive dyskinesia or tardive dystonia includes case series, 1 of which included a double-blind comparison of outcomes when the device was 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.

The evidence for DBS in individuals who have epilepsy or multiple sclerosis includes RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Only 1 RCT was identified for each condition; DBS had a positive impact on some outcomes but not others, and 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.

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. Among the RCTs on DBS for obsessive-compulsive disorder, only 1 reported the outcome of greatest clinical interest, therapeutic response rate, and that study 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>6/2016</td>
<td>BCBSA National medical policy review. Added “upper” to medically necessary statement on DBS for medically unresponsive tremor due to essential tremor or Parkinson disease to clarify that the statement refers to both upper limbs. 6/1/2016</td>
</tr>
<tr>
<td>6/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
</tr>
<tr>
<td>12/2013</td>
<td>BCBSA National medical policy review. New investigational indications described. Effective 12/1/2013. Removed HCPCS codes L8680, L8685-L8688 as they do not meet the intent of the policy</td>
</tr>
<tr>
<td>10/2013</td>
<td>Removed CPT codes 61880, 61885, 61886, 61888, 95970 and diagnosis codes 333.6, 333.83, 333.89 &amp; 723.5 as they do not apply to the policy</td>
</tr>
</tbody>
</table>
No changes to policy statements.


3/2009  BCSBA National medical policy review.  No changes to policy statements.


Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References
2. Blue Cross and Blue Shield Technology Evaluation Center. Bilateral deep brain stimulation of the subthalamic nucleus or the globus pallidus interna for treatment of advanced Parkinson's disease. *TEC Assessment*. 001;Volume 16, Tab 16. PMID


