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 and Dorsal Root Ganglion Stimulation, #472
- Responsive Neurostimulation for the Treatment of Refractory Partial Epilepsy, #716
- Transcranial Magnetic Stimulation as a Treatment of Depression, #297
- Vagus Nerve Stimulation, #474
- Outpatient Electroconvulsive Therapy, #319

Policy

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

Unilateral deep brain stimulation of the thalamus may be considered 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 considered 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 considered MEDICALLY NECESSARY in the following patients:

- Those with Parkinson disease with ALL of the following:
  - A good response to levodopa, AND
  - Motor complications not controlled by pharmacologic therapy; AND
  - one of the following:
    ▪ A minimum 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, OR
    ▪ Parkinson disease for at least 4 years
- Patients older 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 tardive dyskinesia, multiple sclerosis, and post-traumatic dyskinesia, is considered INVESTIGATIONAL.

Deep brain stimulation for the treatment of chronic cluster headaches is considered INVESTIGATIONAL.

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

Medicare HMO BlueSM and Medicare PPO BlueSM Members

Medical necessity criteria and coding guidance can be found through the link below.

National Coverage Determinations (NCDs)

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

Note: To review the specific NCD, please remember to click “accept” on the CMS licensing agreement at the bottom of the CMS webpage.

Prior Authorization Information

Inpatient
- For services described in this policy, precertification/preauthorization IS REQUIRED for all products if the procedure is performed inpatient.

Outpatient
- For services described in this policy, see below for products where prior authorization might be required if the procedure is performed outpatient.

<table>
<thead>
<tr>
<th>Commercial Managed Care (HMO and POS)</th>
<th>Outpatient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>This procedure is performed in the inpatient setting.</td>
</tr>
<tr>
<td>Medicare HMO BlueSM</td>
<td>This procedure is performed in the inpatient setting.</td>
</tr>
<tr>
<td>Medicare PPO BlueSM</td>
<td>This procedure is performed in the inpatient setting.</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>
</thead>
<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,</td>
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</tbody>
</table>
subthalamic nucleus, periventricular, periaqueductal gray), without use of
intraoperative microelectrode recording; first array

<table>
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<tr>
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</thead>
<tbody>
<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; each additional array</td>
</tr>
</tbody>
</table>

**Description**

**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 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.

**Summary**

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.

For individuals who have essential tremor or tremor in Parkinson disease who receive DBS of the thalamus, the evidence includes a systematic review and case series. The relevant outcomes are symptoms, functional outcomes, quality of life (QOL), 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 Parkinson disease (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 randomized controlled trials (RCTs) and systematic reviews. The relevant outcomes are symptoms, functional outcomes, QOL, 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 Parkinson disease of 

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**Summary**

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.

For individuals who have essential tremor or tremor in Parkinson disease who receive DBS of the thalamus, the evidence includes a systematic review and case series. The relevant outcomes are symptoms, functional outcomes, quality of life (QOL), 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 Parkinson disease (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 randomized controlled trials (RCTs) and systematic reviews. The relevant outcomes are symptoms, functional outcomes, QOL, 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 Parkinson disease of
at least four years in duration and uncontrolled motor symptoms found that QOL 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. The relevant outcomes are symptoms, functional outcomes, QOL, 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. The relevant outcomes are symptoms, functional outcomes, QOL, 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. The relevant outcomes are symptoms, functional outcomes, QOL, 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, Liverpool Seizure Severity Scale, or Quality of Life in Epilepsy 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 who receive DBS, the evidence includes observational studies, RCTs and systematic reviews. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. Two RCTs with 15 or more patients have been reported. One RCT found differences in severity of Tourette syndrome for active vs sham at three months while the other RCT did not. Neither study demonstrated improvements in comorbid symptoms of obsessive-compulsive disorder 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. The relevant outcomes are symptoms, functional outcomes, QOL, 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. The relevant outcomes are symptoms, functional outcomes, QOL, 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 might 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. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. Among the RCTs on DBS for obsessive-compulsive disorder, 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.

For individuals who have multiple sclerosis who receive DBS, the evidence includes an RCT. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. One RCT with ten multiple sclerosis patients is insufficient evidence on which to draw conclusions about the efficacy 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. The relevant outcomes are symptoms, functional outcomes, QOL, 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.

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
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<tbody>
<tr>
<td>3/2019</td>
<td>Prior authorization information clarified.</td>
</tr>
<tr>
<td>1/2019</td>
<td>Clarified coding changes. Prior authorization clarified. This procedure is primarily performed in the inpatient setting.</td>
</tr>
<tr>
<td>9/2017</td>
<td>BCBSA National medical policy review. Unilateral or bilateral deep brain stimulation of the globus pallidus or subthalamic nucleus revised to include “OR Parkinson disease for at least 4 years” to medically necessary criteria. New investigational indications described. Clarified coding information. Effective 9/1/2017.</td>
</tr>
<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>
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</tbody>
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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


