MASSACHUSETTS

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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

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 Blue℠ and Medicare PPO Blue℠ 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**.

	Outpatient
Commercial Managed Care (HMO and POS)	This procedure is performed in the inpatient setting.
Commercial PPO and Indemnity	This procedure is performed in the inpatient setting.
Medicare HMO Blue℠	This procedure is performed in the inpatient setting.
Medicare PPO Blue℠	This procedure is performed in the inpatient setting.

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

CPT codes:	Code Description
61863	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
61864	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)
61867	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
61868	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

Description

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, 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 involves the stereotactic placement of an electrode into a central nervous system nucleus (eg, hypothalamus, thalamus, globus pallidus, subthalamic nucleus). Deep brain stimulation is used as an alternative to permanent neuroablative procedures for control of essential tremor and Parkinson disease. Deep brain stimulation 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 deep brain stimulation 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 deep brain stimulation of the thalamus results in clinically significant tremor suppression and that outcomes after deep brain stimulation 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 deep brain stimulation. 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 deep brain stimulation of the globus pallidus interna or subthalamic nucleus, the evidence 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 (a TEC Assessment) concluded that studies evaluating deep brain stimulation of the globus pallidus interna or subthalamic nucleus have consistently demonstrated clinically significant improvements in outcomes (eg, neurologic function). Other systematic

reviews have also found significantly better outcomes after deep brain stimulation 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 quality of life at two years was significantly higher when deep brain stimulation was provided in addition to medical therapy. Meta-analyses of RCTs comparing deep brain stimulation of the globus pallidus interna with deep brain stimulation of the subthalamic nucleus 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 deep brain stimulation of the globus pallidus interna or subthalamic nucleus, 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 deep brain stimulation, 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 quality of life 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 deep brain stimulation, 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 deep brain stimulation and reported that deep brain stimulation 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 7-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 deep brain stimulation. 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 deep brain stimulation 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 deep brain stimulation, 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 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 deep brain stimulation, 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 deep brain stimulation, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A number of case series and several prospective controlled trials evaluating deep brain stimulation in patients with have been published. Two RCTs of deep brain stimulation in the subgenual cingulate cortex and ventral striatum/ventral capsule were terminated for futility. Another RCT of stimulation of the same brain area (ventral striatum/ventral capsule) did not find a statistically significant difference between groups in the primary outcome (clinical response), and adverse psychiatric events occurred more frequently in the treatment group than in the control group. More recently, a controlled crossover trial randomized patients to sham or active stimulation of the anterior limb of the internal capsule 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. Stimulation of the subcallosal (subgenual) cingulate was evaluated in a 2019 sham-controlled within-subject study that found prolonged response in 50% of patients and remission in 30% of patients with treatment resistant depression. Deep brain stimulation for patients with major depressive disorder who have failed all other treatment options is an active area of research, but the brain regions that might prove to be effective for treatment resistant depression have yet to be established. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have obsessive-compulsive disorder who receive deep brain stimulation, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Among the RCTs on deep brain stimulation 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 deep brain stimulation 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 deep brain stimulation, the evidence includes an RCT. Relevant outcome are symptoms, functional outcomes, quality of life, and treatment-related morbidity. One RCT with ten multiple sclerosis patients is insufficient evidence on which to draw conclusions about the efficacy of deep brain stimulation 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 deep brain stimulation, 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 deep brain stimulation for these conditions. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

Date	Action
6/2020	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
5/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
3/2019	Prior authorization information clarified.
1/2019	Clarified coding changes. Prior authorization clarified. This procedure is primarily performed in the inpatient setting.
9/2017	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.
6/2016	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
4/2015	BCBSA National medical policy review. New medically necessary indications described. Effective 4/1/2015.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.

12/2013	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
10/2013	Removed CPT codes 61880, 61885, 61886, 61888, 95970 and diagnosis codes 333.6, 333.83, 333.89 & 723.5 as they do not apply to the policy.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
4/2011	BCBSA National medical policy review. No changes to policy statements.
1/2011	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
4/2010	BCSBA National medical policy review. Changes to policy statements.
1/2010	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
3/2009	BCBSA National medical policy review. No changes to policy statements.
1/2009	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
1/2008	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
7/2007	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
4/2007	BCBSA National medical policy review. Changes to policy statements.
2/2007	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
1/2007	Reviewed - Medical Policy Group - Neurology and Neurosurgery. 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

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