



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](#)
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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**.

	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 BlueSM	This procedure is performed in the inpatient setting.
Medicare PPO BlueSM	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 (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 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 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. DBS has been most thoroughly investigated as an alternative to thalamotomy for unilateral control of essential tremor (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, and 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 and 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 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 have shown the hypothalamic region may be important in the pathogenesis of cluster headaches. Alterations in hormonal or 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 epilepsy, Tourette syndrome, major depressive disorders, and obsessive-compulsive disorder, 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

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. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The systematic review (a TEC Assessment) concluded that there was sufficient evidence that DBS of the thalamus results in clinically significant tremor suppression and that outcomes after DBS were at least as good as thalamotomy. Subsequent studies reporting long-term follow-up have supported the conclusions of the Assessment and found that tremors were effectively controlled 5 to 6 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. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. One of the systematic reviews (a TEC Assessment) concluded that studies of 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 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 1 type of stimulation was 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, 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 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 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 case series, 1 of which included a double-blind comparison of outcomes when the DBS 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.

For individuals who have epilepsy who receive DBS, the evidence includes 1 RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Only 1 RCT was identified; in it, 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.

For individuals who have multiple sclerosis (MS) who receive DBS, the evidence includes 1 RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. One RCT with 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. 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 crossover RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Several small (≤ 15 patients) crossover trials and a 2015 meta-analysis have suggested that DBS may improve outcomes in patients with Tourette syndrome. However, the optimal target for DBS is unknown 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.

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

For individuals who have treatment-resistant depression who receive DBS, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The only double-blind, parallel-group RCT in patients with depression did not find that DBS significantly increased the response rate compared with sham; 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.

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

Policy History

Date	Action
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	BCBSA 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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