PREMERA HMO

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MEDICAL POLICY – 7.01.63

Deep Brain Stimulation

BCBSA Ref. Policy:	7.01.63
Effective Date:	Jul. 1, 2025
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Replaces:	N/A

RELATED MEDICAL POLICIES:

7.01.143	Responsive Neurostimulation for the Treatment of Refractory Focal Epilepsy
7.01.593	Vagus Nerve Stimulation

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Deep brain stimulation (DBS) can be used to treat essential tremor, Parkinson disease, and a movement disorder called dystonia. Deep brain stimulation is used when drugs aren't able to control symptoms. It works by blocking electrical signals in specific areas of the brain that control movement. Surgery is needed to place a thin metal rod, called an electrode, in the brain. (When severe movement affects both sides of the body, an electrode may be implanted on each side of the brain.) The electrode is attached to a small device called a neurostimulator, which is placed under the skin below the collar bone. Batteries power the neurostimulator to send electrical signals to the electrode. 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

Deep Brain Stimulation (DBS) of the thalamus	**Deep brain stimulation (DBS) of the thalamus may be considered medically necessary for either of the following:**
	• Unilateral treatment of disabling, medically unresponsive tremor* due to:
	  ○ Parkinson's disease;
	  OR
	  ○ Essential Tremor
	OR
	• Bilateral treatment of disabling, medically unresponsive tremor* in both upper limbs due to:
	  ○ Parkinson's disease;
	  OR
	  ○ Essential tremor
	
	Note: *See **Definition of Terms**

DBS of the globus pallidus or subthalamic nucleus (unilateral or bilateral)	**Unilateral or bilateral deep brain stimulation (DBS) of the globus pallidus or subthalamic nucleus may be considered medically necessary for either of the following:**
	• Parkinson's disease with ALL of the following:
	  ○ A good response to levodopa; **AND**
	  ○ Motor complications not controlled by drug treatment; **AND**
	  ○ One of the following:
	  ▪ A minimum score of 30 points on the motor portion of the Unified Parkinson Disease Rating Scale (UPDRS) when the individual has been without medication for approximately 12 hours; **OR**
	  ▪ Parkinson's disease for at least 4 years
	OR
	• Primary dystonia** with ALL of the following:
	  ○ Individuals older than 7 years of age; **AND**
	  ○ Chronic, intractable (drug refractory)
	
	Note: **May include generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis)

Application	Investigational

DBS for other disorders	**Deep brain stimulation is considered investigational for:**
	• Other disorders, including but not limited to:
	  ○ Post-traumatic dyskinesia
	  ○ Tardive dyskinesia
	  ○ Chronic cluster headaches
	• Other psychiatric or neurologic diagnoses, including but not limited to:
	  ○ Alcohol addiction
	  ○ Alzheimer disease
	  ○ Anorexia nervosa
	  ○ Chronic pain
	  ○ Depression
	  ○ Epilepsy
	  ○ Multiple sclerosis tremor
	  ○ Obsessive-compulsive disorder
	  ○ Tourette syndrome

Adaptive DBS for Parkinson Disease	**Adaptive deep brain stimulation for Parkinson disease is considered investigational.**

Documentation Requirements
The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include clinical documentation of: • Diagnosis/condition • History and physical examination documenting the severity of the condition • Area planned for deep brain stimulation (thalamus, globus pallidus, or subthalamic nucleus) • Response to levodopa • Unified Parkinson Disease Rating Scale score

Coding

Code	Description
CPT	
61850	Twist drill or burr hole(s) for implantation of neurostimulator or electrodes, cortical.

Code	Description
61860	Craniectomy or craniotomy for implantation of neurostimulator electrodes, cerebral, cortical
61863	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
61864	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; 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 (e.g., 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 (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; each additional array (List separately in addition to primary procedure)
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays
HCPCS	
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
L8680	Implantable neurostimulator electrode, each
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

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
- Inadequate control by maximal dosage of medication for at least three months before implant

Adaptive DBS (aDBS) is a closed-loop system incorporating feedback from brain signals to dynamically adjust stimulation parameters. It is a more personalized approach to treatment of advanced disease and holds promise for reducing stimulation duration and energy consumption while treating motor related issues such as dyskinesia. (The FDA submission for aDBS by Medtronic was as an optional programming feature for Parkinson's Disease in existing devices. It was not studied in bilaterally implanted neurostimulators, and the labeling instructs not to use aDBS with more than one implanted neurostimulator).

Contraindications to deep brain stimulation include:

- Individuals who are not good surgical risks because of unstable medical problems or because of the presence of a cardiac pacemaker
- Individuals who have medical conditions that require repeated magnetic resonance imaging
- Individuals who have dementia that may interfere with the ability to cooperate
- Individuals who have had botulinum toxin injections within the last six months

Plans may need to consider accessory or software adjustments for individuals with a pre-existing DBS on a case by case basis. Parkinson disease is a complex condition and might entail a complex system of care particularly when the disease has advanced.

Evidence Review

Description

Deep brain stimulation (DBS) involves the stereotactic placement of an electrode into a central nervous system nucleus (e.g., 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.

Background

Deep Brain Stimulation

DBS involves the stereotactic placement of an electrode into the brain (i.e., 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 individual 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, the use of bilateral stimulation using two electrode arrays has also been investigated in individuals with bilateral, severe symptoms. After implantation, noninvasive programming of the neurostimulator can be adjusted to the individual's symptoms. This feature may be important for individuals 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.

Essential Tremor and Tremor in Parkinson Disease

DBS has been investigated as an alternative to permanent neuroablative procedures, such as thalamotomy and pallidotomy, and pharmacologic therapy. DBS has been most thoroughly investigated as an alternative to thalamotomy for unilateral control of essential tremor (ET) and tremor associated with Parkinson's disease.. 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.

Primary and Secondary Dystonia

DBS has also been investigated in individuals 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. 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.

Summary of Evidence

For individuals who have ET or tremor in PD 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 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 an improvement in the net health outcome.

For individuals who have symptoms (e.g., speech, motor fluctuations) associated with PD (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 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 DBS of the GP or STN have consistently demonstrated clinically significant

improvements in outcomes (e.g., neurologic function). Other systematic reviews have also found significantly better outcomes after DBS than after a control intervention. An RCT in individuals with levodopa-responsive PD of at least four years in duration and uncontrolled motor symptoms found that quality of life 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 superior to the other. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with symptoms associated with Parkinson disease who receive adaptive deep brain stimulation of the GPi or STN, the evidence includes one RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. There is currently one ongoing RCT assessing the feasibility and efficacy of adaptive deep brain stimulation (aDBS) for control of Parkinson disease symptoms. One RCT assessed the feasibility and efficacy of aDBS for control of Parkinson disease symptoms. The primary efficacy outcome measured "On" time without dyskinesia, with success rates of 78.9% for single-threshold aDBS and 91% for dual-threshold aDBS. Safety analysis showed that overall 78.8% of patients experienced adverse events, 56.5% had device-related events, and 17.6% had serious adverse events, including one participant with 2 severe device-related injuries. The evidence is insufficient to determine that the technology results in an 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. 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 six 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 an 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. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. 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 these may have been underpowered. Additional studies, especially RCTs or other controlled studies, are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have epilepsy who receive DBS, 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 individuals were identified. The first RCT (N=110) 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 individuals). 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 individuals; 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 individuals who continued follow-up. The second RCT (N=16) showed a benefit with DBS. Many 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 individual outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have Tourette syndrome (TS) who receive DBS, 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 individuals have been reported. One RCT found differences in severity of TS for active versus sham at three months while the other RCT did not. Neither study demonstrated improvements in comorbid symptoms of obsessive-compulsive disorder (OCD) or depression. Both studies reported high rates of serious adverse events. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have cluster headaches or facial pain who receive DBS, the evidence includes a systematic review, randomized crossover study, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The systematic review included an individual patient data meta-analysis of 34 patients, showing a significant reduction in pain intensity at 3 months following DBS for chronic facial pain; data for follow-up beyond 3 months were not eligible for statistical analysis. In an RCT of 11 individuals with severe, refractory, chronic cluster headache, 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 that the technology results in an improvement in the net health outcome.

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. A number of case series and several prospective controlled trials evaluating DBS have been published. Two RCTs of DBS 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 individuals 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 individuals 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 individuals and remission in 30% of individuals with treatment resistant depression. DBS for individuals 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 that the technology results in an improvement in the net health outcome.

For individuals who have OCD who receive DBS, the evidence includes meta-analyses of RCTs . Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Among the RCTs on DBS for OCD included in meta-analyses, only one has reported the outcome of 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 that the technology results in an improvement in the net health outcome.

For individuals who have other neurologic or psychiatric disorders who receive DBS, the evidence includes a number of nonrandomized studies or RCTs in individuals with multiple sclerosis (MS), chronic pain, or alcohol use disorder. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. One RCT with ten MS individuals, two RCTs in individuals with chronic pain, and one RCT in individuals with treatment-refractory alcohol use disorder is insufficient evidence on which to draw conclusions about the efficacy of DBS in these populations. Additional trials are required. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have anorexia nervosa, alcohol addiction, Alzheimer disease, Huntington's disease, or chronic pain who receive DBS, the evidence includes case series; RCTs are needed to evaluate the efficacy of DBS for these conditions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in **Table 1**. Included are randomized controlled trials with at least 40 participants, excluding trials on DBS for PD.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
Epilepsy			
NCT04164056	Hippocampal and Thalamic deep brain stimulation for Bilateral Temporal Lobe Epilepsy	80	Sep 2024
NCT03900468[a]	Medtronic Deep Brain Stimulation Therapy for Epilepsy Post-Approval Study (EPAS)	140	Mar 2028
NCT06248333	Subthalamic Nucleus Electrical Stimulation for Drug-resistant Focal Motor Epilepsy (STEM)	33	Jan 2026
NCT06364085	EPI-BOOST: Enhancing Epilepsy Management With Precision Deep Brain Stimulation	40	Jun 2026
Huntington's Disease			
NCT04244513[a]	Deep Brain Stimulation Treatment for Chorea in Huntington's Disease	40	Dec 2023
Obsessive-Compulsive Disorder			
NCT02773082[a]	Reclaim Deep Brain Stimulation Therapy for Obsessive-Compulsive Disorder (OCD)	50	Jan 2030
NCT02844049	European Study of Quality of Life in Resistant OCD Patients Treated by subthalamic nucleus deep brain stimulation	60	Apr 2027
NCT05995951	Deep Brain Stimulation Surgery for the Treatment of Refractory Obsessive-Compulsive Disorder	10	Sept 2025
Treatment Resistant Depression			
NCT03653858[a]	Controlled Randomized Clinical Trial to Assess Efficacy of Deep Brain Stimulation of the slMFB in Patients With Treatment Resistant Major Depression (FORSEEIII)	47	Jun 2025
NCT06096207	DBS for Depression	20	Oct 2038
Alzheimer Disease			

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT03622905	ADvance II Study: DBS-f in Patients With Mild Alzheimer's Disease	74	Feb 2024
NCT05882344	Deep Brain Stimulation for Alzheimer's	2	Oct 2028
NCT05762926	Non-invasive Brain Stimulation by Transcranial Pulse Stimulation as a Coadjunctive Treatment in Alzheimer's Disease	50	May 2024
Unpublished			
NCT04181229	Deep Brain Stimulation Post Failed Vagal Nerve Stimulation for the Treatment of Drug-Resistant Epilepsy in Children	25	Mar 2023
NCT02076698	Deep Brain Stimulation of the Anterior Nucleus of the Thalamus in Epilepsy	62	Nov 2021

NCT: national clinical trial

[a] Denotes industry-sponsored or cosponsored trial

Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2014 Input

In response to requests, input was received from two academic medical centers and two physician specialty societies while this policy was under review in 2014. Input supported the use of bilateral DBS in individuals with medically unresponsive tremor in both limbs.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Neurology

Essential Tremor

In 2011, The American Academy of Neurology (AAN) updated its guidelines on the treatment of ET which were reaffirmed in 2022.[76] This update did not change the conclusions and recommendations of the AAN (2005) practice parameters on DBS for ET.[77] 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 on the risk/benefit ratio of bilateral vs unilateral DBS in the treatment of limb tremor. There was insufficient evidence to make recommendations on the use of thalamic DBS for head or voice tremor (level U, treatment is unproven).

Parkinson Disease

In 2018, the AAN affirmed the guideline developed by the Congress of Neurological Surgeons.[78] **(See Table 2)**

Tourette Syndrome

Guidelines from AAN (2019, reaffirmed 2022) provide recommendations on the assessment for and use of DBS in adults with severe, treatment-refractory tics.[79] The AAN notes that individuals with severe TS resistant to medical and behavioral therapy may benefit from DBS, but there is no consensus on the optimal brain target. Brain regions that have been stimulated in individuals with TS include the centromedian thalamus, the globus pallidus internus (ventral and dorsal), the globus pallidus externus, the STN, and the ventral striatum/ventral capsular nucleus accumbens region. The AAN concludes that DBS of the anteromedial globus pallidus is possibly more likely than sham stimulation to reduce tic severity.

American Society for Stereotactic and Functional Neurosurgery

Obsessive-Compulsive Disorder

In 2021, the American Society for Stereotactic and Functional Neurosurgery and the Congress of Neurological Surgeons updated their 2014 guidelines on DBS for OCD.[80] The document concluded that there was 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 or bed nucleus of stria terminalis DBS for medically refractory OCD. It also concluded that the evidence on unilateral DBS was insufficient.

Refractory Epilepsy

In 2022, the American Society for Stereotactic and Functional Neurosurgery published a position statement on DBS for medication-refractory epilepsy.[81] Indications for deep brain stimulation include confirmed diagnosis of epilepsy (focal onset seizures with or without generalization), failure to achieve seizure control after two or more appropriately dosed seizure medications, seizures with localized onset in a region that cannot be resected or for which surgical resection has failed, or focal-onset seizures with a nonlocalized or unclear region of onset.

Congress of Neurologic Surgeons

Parkinson Disease

In 2018, evidence-based guidelines from the Congress of Neurologic Surgeons, affirmed by the AAN, compared the efficacy of bi-lateral DBS of the subthalamic nucleus and globus pallidus internus for the treatment of individuals with Parkinson disease.[78]

Table 2. Recommendations of the Congress of Neurologic Surgeons for DBS for Parkinson Disease

Goal	Most Effective Area of Stimulation (subthalamic nucleus or globus pallidus internus)	Level of Evidence
Improving motor symptoms	subthalamic nucleus or globus pallidus internus are similarly effective	I
Reduction of dopaminergic medication	subthalamic nucleus	I
Treatment of "on" medication dyskinesias	globus pallidus internus if reduction of medication is not anticipated	I
Quality of life	no evidence to recommend one over the other	I
Lessen impact of DBS on cognitive decline	globus pallidus internus	I
Reduce risk of depression	globus pallidus internus	I
Reduce adverse effects	insufficient evidence to recommend one over the other	Insufficient

DBS: Deep brain stimulation

National Institute for Health and Care Excellence

The United Kingdom's NICE has published guidance documents on DBS, as discussed in the following subsections.

Tremor and Dystonia

In 2006, NICE made the same statements about use of DBS for treatment of both tremor and dystonia.[82] Unilateral and bilateral stimulation of structures responsible for modifying movements, such as the thalamus, globus pallidus, and the STN, which interact functionally with the substantia nigra, are included in both guidance statements. The guidance stated: "Current evidence on the safety and efficacy of DBS for tremor and dystonia (excluding Parkinson's disease) appears adequate to support the use of this procedure."

Refractory Chronic Pain Syndromes (Excluding Headache)

In 2011, guidance from NICE indicated there is evidence that DBS for refractory chronic pain (excluding headache) is associated with serious risks.[83] However, the procedure is "efficacious in some patients refractory to other treatments." 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 Cephalalgias

In 2011, guidance from NICE indicated that the evidence on the efficacy of DBS for intractable trigeminal autonomic cephalalgias (e.g., cluster headaches) was "limited and inconsistent, and the evidence on safety shows that there were serious but well-known adverse effects."[84]

Refractory Epilepsy

In 2020, guidance from NICE indicated that the evidence on the efficacy and safety of DBS for refractory epilepsy (for anterior thalamic targets) was limited in both quantity and quality, and "this procedure should only be used with special arrangements for clinical governance, consent, and audit or research".[85] For targets other than the anterior thalamus, NICE recommends that "this procedure should only be used in the context of research".

Parkinson Disease

In 2003, NICE stated that the evidence on the safety and efficacy of DBS for treatment of PD "appears adequate to support the use of the procedure."[86] The guidance noted that DBS should only be offered when PD is refractory to best medical treatment.

Medicare National Coverage

Effective for services furnished in April 2003, Medicare covers unilateral or bilateral thalamic ventralis intermedius nucleus DBS for the treatment of ET and/or parkinsonian tremor and unilateral or bilateral STN or GBi DBS for the treatment of PD when the following conditions are met[87]:

- Devices must be approved by the US Food and Drug Administration (FDA) for "DBS or devices used in accordance with FDA-approved protocols governing Category B Investigational Device Exemption (IDE) DBS clinical trials."
- For thalamic ventralis intermedius nucleus 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 GBi 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 (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"

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 approved by the FDA through the pre-market approval process for DBS. 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 individual to turn the neurostimulator on and off, or change between high and low settings.

The FDA-labeled indications for Activa were originally limited to unilateral implantation of the device for the treatment of tremor, but the indications have evolved over time. In 2002, the FDA-labeled indications were expanded to include bilateral implantation as a treatment to decrease the symptoms of advanced PD 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." In 2018, the DBS system received an expanded indication as an adjunctive therapy for epilepsy (P960009-S219). Other DBS systems are described in **Table 2**.

Table 2. Deep Brain Stimulation Systems

System	Manufacturer	FDA Product Code	PMA or HDE	Approval Date	Indications
Activa Deep Brain Stimulation Therapy System	Medtronic	MBX	P96009	1997	Unilateral or bilateral stimulation of the internal globus pallidus or subthalamic nucleus for

System	Manufacturer	FDA Product Code	PMA or HDE	Approval Date	Indications
					symptoms of Parkinson disease or primary dystonia
Reclaim DBS Therapy for Obsessive Compulsive Disorder	Medtronic		H050003	2009	Bilateral stimulation of the anterior limb of the internal capsule for severe obsessive-compulsive disorder
Brio Neurostimulation System	St. Jude Medical	NHL	P140009	2015	Parkinsonian tremor (subthalamic nucleus) and essential tremor (thalamus)
Infinity DBS	Abbott Medical/St. Jude Medical	PJS	P140009	2016	Parkinsonian tremor
Vercise DBS System	Boston Scientific	NHL	P150031	2017	Moderate-to-advanced levodopa-responsive PD inadequately controlled with medication alone
Medtronic DBS System for Epilepsy	Medtronic	MBX	P960009-S219	2018	Expanded indication for epilepsy with bilateral stimulation of the anterior nucleus of the thalamus
Percept PC Deep Brain Stimulation	Medtronic	MHY	P960009-S	2020	Records brain signals while delivering therapy for PD or primary dystonia
Vercise Genus DBS System	Boston Scientific	NHL	P150031-S034	2021	Stimulation of the subthalamic nucleus and globus pallidus for PD
SenSight Directional Lead System	Medtronic	MHY	P960009	2021	Unilateral or bilateral stimulation for PD, tremor, dystonia, and epilepsy
BrainSense Adaptive Deep Brain Stimulation	Medtronic	MHY	P960009	2025	Automatically adjusted therapeutic stimulation to maximize reduction of PD symptoms

DBS: deep brain stimulation; HDE: humanitarian device exemption; OCD: obsessive-compulsive disorder; PD: Parkinson disease; PMA: premarket approval

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History

Date	Comments
06/25/98	Add to Surgery Section - New Policy
01/07/99	Coding Update - 1999 CPT Coding Release.
05/09/00	Replace Policy - Policy reviewed; new information added on bilateral stimulation and different sites of stimulation; underlying policy statement unchanged.
06/02/00	Replace Policy - Added cross-references to other stimulation policies.
04/09/02	Replace Policy - Policy updated based on TEC Assessment; policy statement revised to include a broader range of patients w/Parkinson's disease.
10/16/03	Replace Policy - Policy revised with focus on new FDA-labeled indication for primary refractory dystonia. Rest of policy statement is unchanged.
01/01/04	Replace Policy - CPT code updates only.
05/11/04	Replace Policy - Policy reviewed, additional CPT codes added. No change to policy statement.
06/14/05	Replace Policy - Policy revised with information and policy statement added on deep brain stimulation for cluster headaches. The previous policy statements are unchanged.
02/06/06	Codes updated - No other changes.
06/16/06	Replace Policy - Policy revised with literature review; references added; policy statements are unchanged. Scope and Disclaimer language updated.
01/26/07	Codes Updated - No other changes.
06/15/07	Cross Reference Update - No other changes.
11/13/07	Replace Policy - Policy revised with literature review; references added. Policy statement updated with treatment of other psychiatric or neurologic disorders is considered investigational.
12/11/07	Cross Reference Updated - No other changes.
04/08/08	Codes Updated - Added 61860, no other changes
12/16/08	Replace Policy - Policy statement clarified to state that score of 30 points must be within the Motor section of the UPDRS.

Date	Comments
05/12/09	Replace Policy - Policy updated with literature search, no change to the policy statement. References added.
04/13/10	Cross Reference Update - No other changes.
06/13/11	Replace Policy - Policy updated with literature review; references 27-31 added. No change in policy statements.
04/17/12	Related Policies updated: 7.01.546 added to replace 7.01.25 which has been deleted.
08/20/12	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.
08/27/12	Update Related Policy – 7.01.20 is added. Update Coding Section – ICD-10 effective dates are now 10/01/2014.
10/17/12	Update Related Policies – Add 6.01.54.
10/14/13	Replace policy. Policy updated with literature review through May 20, 2013; reference 20 added; anorexia nervosa, alcohol addiction, and chronic pain added as investigational.
12/08/14	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.
01/26/15	Update Related Policies. Add 7.01.143.
12/08/15	Annual Review. Policy reviewed. No new references added. Policy statement unchanged.
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.
01/01/18	Coding update, removed CPT code 0169T as it was terminated 1/1/17.
07/01/18	Annual Review, approved June 22, 2018. Policy updated with literature review through February 2018; references 6-10, 17, 27-29, 31-32, 34, and 59 added. Policy statements reformatted for greater clarity.
03/01/19	Minor update, added Documentation Requirements section.

Date	Comments
07/01/19	Annual Review, approved June 4, 2019. Policy updated with literature review through February 2019; references added. Policy statements unchanged.
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.
07/02/20	Delete policy.
11/01/20	Policy reinstated effective February 5, 2021, approved October 13, 2020. Policy updated with literature review through March, 2020; references added. Policy statements unchanged.
07/01/21	Annual Review, approved June 1, 2021. Policy updated with literature review through March 15, 2021; references added. Policy statements unchanged. Added HCPC codes C1767 and C1778.
07/01/22	Annual Review, approved June 13, 2022. Policy updated with literature review through March 3, 2022; references added. Policy statements unchanged.
07/01/23	Annual Review, approved June 12, 2023. Changed the wording from "patient" to "individual" throughout the policy for standardization.
07/01/24	Annual Review, approved June 24, 2024. Policy updated with literature review through February 22, 2024; references added. Policy statements unchanged.
09/11/24	Minor update to related policies. 7.01.20 was replaced with 7.01.593 Vagus Nerve Stimulation.
07/01/25	Annual Review, approved June 10, 2025. Policy updated with literature review through March 4, 2025; references added. Added investigational policy statement for adaptive deep brain stimulation in Parkinson disease.

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.