MEDICAL POLICY



An independent licensee of the Blue Cross Blue Shield Association

Medical Policy Title	Deep Brain Stimulation
Policy Number	7.01.23
Current Effective Date	April 17, 2025
Next Review Date	April 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to <u>Product Disclaimer</u>)

POLICY STATEMENT(S)

- I. Unilateral or bilateral deep brain stimulation of the ventral intermediate nucleus (VIM) thalamus is a **medically appropriate** treatment option in the management of disabling, medically unresponsive essential tremor or tremor due to Parkinson's disease when **BOTH** of the following criteria are met (Disabling, medically unresponsive tremor is defined as both of the following):
 - A. tremor causing significant limitation in daily activities; and
 - B. inadequate control with maximal dosage of medication for at least three (3) months before implant.
- II. Conventional bilateral deep brain stimulation of the subthalamic nucleus (STN) or globus pallidus interna (GPi) is a **medically appropriate** treatment option for Parkinson's disease when **ALL** of the following criteria are met:
 - A. The patient has a good response to levodopa;
 - B. Motor complications are not controlled by pharmacologic therapy; and
 - C. **ONE** of the following:
 - 1. 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**
 - 2. Parkinson's disease for at least four (4) years.
- III. Conventional unilateral or bilateral deep brain stimulation of the STN or GPi is **medically appropriate** when the following criteria are met:
 - A. individual is seven (7) years of age or older;
 - B. individual has chronic, intractable primary dystonia, including any of following indications:
 - 1. generalized or segmental dystonia,
 - 2. hemidystonia; **or**
 - 3. cervical dystonia (torticollis).
- IV. Unilateral or bilateral deep brain stimulation of the anterior nucleus of the thalamus (ANT) is **medically appropriate** when **ALL** of the following criteria are met:

Medical Policy: Deep Brain Stimulation Policy Number: 7.01.23

Page: 2 of 16

- A. A confirmed diagnosis of epilepsy;
- B. 18 years of age or older;
- C. Focal partial onset seizures with or without generalized seizure;
- Refractory to medical therapy defined as failure to adequately control seizures after two (2) (or more) appropriate and adequately dosed anti-seizure medications or intolerance to antiseizure medications;
- E. Currently having an average of three (3) or more disabling seizures (e.g., motor partial seizures, complex partial seizures, or secondary generalized seizures) per month over the most recent three (3) months; **and**
- F. Absence of progressive neurological conditions such as neurodegenerative disease.
- V. Device Repair
 - A. Repair of a medically necessary DBS or components not under warranty will be considered **medically appropriate** when the following criteria are met:
 - 1. Physician documentation includes **ALL** of the following:
 - a. date of device implantation/initiation;
 - b. manufacturer warranty information, if applicable; and
 - c. attestation that the patient has been compliant with the use of device and will continue to benefit from the use of device;
 - 2. The device is no longer functioning adequately; and **BOTH** of the following criteria are met:
 - a. inadequate function interferes with activities of daily living; and
 - b. repair is expected to make the equipment fully functional (as defined by manufacturer).
 - B. Repair of equipment damaged due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

VI. Device Replacement

- A. Replacement of a medically necessary DBS or components not under warranty will be considered **medically appropriate** when **EITHER** of the following criteria are met:
 - 1. The device is no longer functioning adequately and has been determined to be non-repairable or the cost of the repair is in excess of the replacement cost;
 - 2. There is documentation that a change in the patient's condition makes the present unit non-functional and improvement is expected with a replacement unit.

Medical Policy: Deep Brain Stimulation Policy Number: 7.01.23

Page: 3 of 16

- B. The replacement of a properly functioning DBS its components or accessories is considered not medically necessary. This includes, but is not limited to, replacement desired due to advanced technology or in order to make the device more aesthetically pleasing;
- C. The replacement of equipment damaged or lost due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.
- VII. Accessories or components for [device] that are considered not medically necessary or investigational by peer-reviewed literature will also be considered as **not medically necessary or investigational** by the Health Plan.
- VIII. Directional deep brain stimulation (e.g., St. Jude Medical Infinity DBS System and Vercise DBS System) is **investigational** for all indications.
- IX. Conventional deep brain stimulation is **investigational** for all conditions not specifically identified in Policy Statements I through IV, including, but not limited to, the following conditions:
 - A. Multiple sclerosis tremor;
 - B. Post-traumatic dyskinesia;
 - C. All other movement disorders;
 - D. Chronic pain syndromes, including cluster headache;
 - E. Tardive dyskinesia;
 - F. Tourette syndrome;
 - G. Dementias, including Alzheimer's disease;
 - H. Eating disorders, including anorexia nervosa;
 - I. Alcohol addiction;
 - J. Treatment-resistant depression;
 - K. Treatment-resistant obsessive-compulsive disorder.
- X. Deep brain stimulation is contraindicated and therefore, **not medically necessary** for **ANY** individuals in the following situations:
 - A. Not a good surgical candidate due to unstable medical conditions;
 - B. Presence of a cardiac pacemaker;
 - C. A medical condition that requires repeated magnetic resonance imaging (MRI);
 - D. Presence of dementia that may interfere with the ability to cooperate; or
 - E. Recent treatment with botulinum toxin injections within the last six (6) months.

RELATED POLICIES

Medical Policy: Deep Brain Stimulation Policy Number: 7.01.23 Page: 4 of 16

Corporate Medical Policy

07.01.103 Responsive Neurostimulation for the Treatment of Refractory Focal Epilepsy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

- I. This medical policy does not address occipital nerve stimulation for chronic migraines or occipital neuralgia. In occipital nerve stimulation, the neurostimulator delivers electrical impulses via insulated lead wires tunneled under the skin near the occipital nerves at the base of the head.
- II. Bilateral stimulators may be implanted simultaneously or in staged procedures.

DESCRIPTION

Deep brain stimulation (DBS) has been investigated as an alternative to permanent neuro-ablative procedures, such as thalamotomy and pallidotomy. The procedure involves the stereotactic placement of an electrode into a targeted region of the brain. The electrode is then attached, via a cable/wire, to a programmable stimulator implanted subcutaneously. DBS is designed to turn off overactive brain regions without destroying them. The immediate advantage of DBS over conventional destructive surgery is that the lesions are titratable and, hence, reversible. After implantation, noninvasive programming of the neurostimulator can be adjusted to the individual's symptoms.

The effect of DBS depends on where the electrodes are placed. The three common target sites are the VIM thalamus, STN and GPi. Whereas unilateral/bilateral DBS of the thalamus is utilized to treat essential tremor or tremors of advanced Parkinson's disease, DBS of the STN or of the GPi is used for treatment of the entire constellation of Parkinsonian symptoms (e.g., tremor, rigidity, and bradykinesia). DBS is performed at specialty centers.

DBS has also been investigated for the treatment of primary dystonia, defined as a neurological movement disorder characterized by involuntary and painful muscle contractions and contortions. Dystonia can be classified according to cause and the bodily distribution of symptoms. Primary or idiopathic dystonia is not associated with any other pathology, whereas secondary dystonia is caused by a known insult (e.g., trauma, infarct, stroke) to the basal ganglia. Generalized dystonia affects a wide range of body areas, while focal dystonia affects specific body parts (e.g., spasmodic torticollis/cervical dystonia, blepharospasm). Dystonia is the third most common movement disorder, behind Parkinson's disease and essential tremor. Unless contraindicated, DBS of either the STN or GPi requires a bilateral procedure.

In addition to essential tremors, Parkinson's disease, and primary dystonia, DBS is also being investigated for disorders such as major depression, cluster headaches, chronic pain syndromes, Tourette syndrome, epilepsy, and obsessive-compulsive disorder.

Unified Parkinson's Disease Rating Scale (UPDRS)

Medical Policy: Deep Brain Stimulation Policy Number: 7.01.23 Page: 5 of 16

The Unified Parkinson's Disease Rating Scale (UPDRS) is the most widely applied rating instrument for the evaluation of a person with Parkinson's Disease to determine disease severity. The total UPDRS score includes 31 items contributing to three (3) subscales: (I) Mentation, Behavior and Mood; (II) Activities of Daily Living; and (III) Motor Examination. The UPDRS does not assess general cardiovascular fitness and provides only limited information on functional performance relative to daily activities.

Conventional DBS

Conventional DBS systems use ring-shaped electrodes, which generate an approximately spherical electrical field. In these systems, programming of polarity and stimulation pulse parameters allows only limited control of the shape of the volume of tissue activated. While physicians try to target a very specific area of the brain with conventional DBS, there is a risk of stimulating neighboring regions as they cannot steer the stimulation precisely.

Directional DBS

Directional DBS systems use novel lead designs with segmented, multi-contact electrodes that allow for the activation of individual electrode contacts which also allow the physician to specify the exact amount of current needed for every contact of the electrode. By activating specific electrode contacts and defining the amount of stimulation for each contact, stimulation precision is significantly increased. More precise stimulation is thought to reduce side effects of DBS, such as muscle contractions, dysarthria, and cognitive or behavioral disturbances sometimes seen in conventional DBS.

SUPPORTIVE LITERATURE

Unilateral Stimulation of the Thalamus

Schuurman et al. (2008) reported on 5-year follow-up of 68 patients comparing thalamic stimulation with thalamotomy for the treatment of tremor due to Parkinson's disease (n=45 patients), essential tremor (n=13 patients), and multiple sclerosis (MS; n=10 patients). Forty-eight (71%) patients were assessed at five years: 32 with Parkinson's disease, 10 with essential tremor, and 6 with MS. The Frenchay Activities Index, the primary study outcome measure, was used to assess change in functional status. Secondary measures included tremor severity, complication frequency, and patient-assessed outcomes. The mean difference between interventions, as measured on the Frenchay Activities Index, favored thalamic stimulation at all time points: 4.4 (95% confidence interval [CI], 1.1 to 7.7) at 6 months, 3.3 (95% CI, -0.03 to 6.6) at 2 years, and 4.0 (95% CI, 0.3 to 7.7) at 5 years. The procedures had similar efficacy for suppressing tremors. The effect of thalamic stimulation diminished in half of the patients with essential tremor and MS. Neurologic adverse effects were higher after thalamotomy. Subjective assessments favored stimulation.

Hariz et al. (2008) evaluated outcomes of thalamic deep brain stimulation in patients with tremorpredominant Parkinson's disease who participated in a multicenter European study. The authors reported that at 6 years post-surgery, tremor was still effectively controlled and appendicular rigidity and akinesia remained stable compared with baseline.

Bilateral Stimulation

Medical Policy: Deep Brain Stimulation Policy Number: 7.01.23 Page: 6 of 16

Jost et al. (2023) conducted an observational study of the long-term effect of bilateral DBS on the subthalamus nucleus and its effects on quality of life, motor functions, and medication requirements for patients with advanced Parkinson's. The final analysis included 108 patients with 62 receiving DBS and 46 receiving medications matched to a sub cohort of 25 patients per group. At the five years follow up, the Parkinson's Disease Questionnaire 8 (PDQ-8) and ADL scores worsened only in the medication group, while remaining stable in the DBS group. The group that received DBS also experienced favorable effects on motor complications.

Epilepsy

Results of Medtronic's Stimulation of the Anterior Nuclei of Thalamus for Epilepsy (SANTÉ) trial (Fisher et al., 2010) showed promising outcomes on the adjunct use of DBS of the ANT over placebo stimulation for patients suffering from severe, refractory, partial-onset seizures. All subjects underwent DBS implantation followed by three months of randomized and blinded active stimulation (n=54) or no stimulation (n=55), then followed by nine months of active stimulation for all subjects. Two years after implantation of the device, seizures were reduced by a median 56% compared with baseline, and 14 patients (12.7%) became seizure-free for at least six months. Longer-term studies were needed to better define its safety and efficacy, as well as the subset of patients who would benefit most from this treatment.

Salanova and others published a long-term follow-up study of the SANTÉ trial in 2015. Beginning 13 months following device implantation, 105 subjects receiving active stimulation were followed for an additional four years. The authors reported that for subjects with at least 70 diary entries recorded at one (1) year (n=99), median change for seizure frequency from baseline decreased by 41% (p <0.001), and by 69% at five (5) years (n=59; p <0.001). For the same population, reduction in the most severe type of seizure was 39% at one year (p <0.001) and 75% at five years (p <0.001). During the 5-year study, 17 of 109 subjects (16%) reported a 6-month seizure-free interval. A 2-year seizure-free interval was reported for 6 of 109 subjects (5.5%). Mean improvement in the Liverpool Seizure Severity Score (LSSS) was 13.4 at one year and 18.3 at five years (p <0.001 for both). Similarly, results from the Quality of Life in Epilepsy-31 (QOLIE-31) tool improved from baseline by 5.0 points at one (1) year and 6.1 points at (5) five years (p <0.001 for both). A change of 5 points on this measure is considered clinically significant and was experienced by 46% and 48% of subjects at one and five years. Device-related adverse events included site infection, leads not within the target area, depression and memory impairment. This study demonstrated significant long-term benefit from DBS for individuals with epilepsy, although the study was relatively small and unblinded.

On April 27, 2018, the FDA approved the Medtronic DBS System for Epilepsy for bilateral stimulation of the anterior nucleus of the thalamus (ANT) based on the SANTÉ trials as an adjunctive therapy for reducing the frequency of seizures in individuals 18 years of age or older who are diagnosed with epilepsy characterized by partial-onset seizures, with or without secondary generalization, that are refractory to three or more antiepileptic medications. The FDA indicated that the Medtronic DBS System for Epilepsy has demonstrated safety and effectiveness for patients who average six (6) or more seizures per month over the three (3) most recent months prior to implant of the DBS system (with no more than 30 days between seizures). The Medtronic DBS System for Epilepsy has not been evaluated in patients with less-frequent seizures.

Medical Policy: Deep Brain Stimulation Policy Number: 7.01.23 Page: 7 of 16

The effect of deep brain stimulation of the anterior nuclei of the thalamus (ANT-DBS) after implantation has been reported as approximately 50% seizure frequency reduction in approximately 60% of patients (Herrman et al., 2019) and the seizure frequency reduction increased over the following ten years (Salanova, 2018 and Salanova et al., 2021). Multiple literature reviews of randomized and blinded clinical trials and case series with high-quality data support the use of DBS for the treatment of medically refractory epilepsy.

Other Indications

Published clinical trials have not provided evidence to support the efficacy and safety of DBS for other conditions, including, but not limited to multiple sclerosis, post-traumatic dyskinesia, treatment-resistant depression, Alzheimer's disease, and Tourette syndrome; or for bilateral DBS of the VIM thalamus. Studies of DBS for the treatment of chronic pain have not provided evidence that DBS is an effective treatment method over already-established treatment methods.

PROFESSIONAL GUIDELINE(S)

In 2003, the National Institute for Health and Care Excellence (NICE) published guidance on DBS for Parkinson's Disease stating that the evidence on the safety and efficacy of deep brain stimulation for treatment of Parkinson's disease "appears adequate to support the use of the procedure." The guidance noted that deep brain stimulation should only be offered when Parkinson's disease is refractory to best medical treatment.

The American Academy of Neurology (AAN) 2011 updated its guidelines on the treatment of essential tremor, which were reaffirmed in 2022. 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 versus unilateral deep brain stimulation in the treatment of limb tremor. There was insufficient evidence to make recommendations on the use of thalamic deep brain stimulation for head or voice tremor (level U, treatment is unproven).

In December of 2021, the American Society of Stereotactic and Functional Neurosurgery (ASSFN) published the following position statement: "Deep brain stimulation (DBS) of the bilateral anterior nucleus of the thalamus (ANT) is a Food and Drug Administration (FDA)-approved, safe, and efficacious treatment option for patients with refractory focal epilepsy" who meet specific criteria.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) has approved the Activa Tremor Control System (Medtronic, Inc.) for DBS. The original 1997 FDA-labeled indications were limited to unilateral implantation of the device for the treatment of tremor, in January 2002, the FDA-labeled indications were expanded to include bilateral implantation as a treatment to decrease the symptoms of advanced Parkinson's disease that are not controlled by medication. In February 2016, the FDA expanded the approval for Medtronic's DBS for Parkinson's disease. The expanded approval covers individuals who have had a Parkinson's diagnosis for four years and who have recently developed motor complications or have long-standing motor complications that cannot be controlled with drugs.

Medical Policy: Deep Brain Stimulation Policy Number: 7.01.23 Page: 8 of 16

The expanded approval is based on data from the EARLYSTIM clinical study (Schuepbach WM et al., 2013), which found that individuals treated with Medtronic DBS Therapy and best medical therapy (BMT) reported a mean improvement of 26 percent in their disease-related quality of life at two years, compared to a one percent decline in individuals treated with BMT alone. In a study of individuals with longer-standing motor complications, DBS individuals' quality of life improved 20 percent from baseline to six months, compared to no improvement in the individuals treated with BMT alone.

In April 2003, the FDA gave Humanitarian Device Exemption (HDE) approval to the Activa Therapy System for the unilateral or bilateral stimulation of the internal STN or GPi, to aid in the management of chronic, intractable (drug-resistant) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia in individuals seven years of age or older. In 2016, the FDA identified that the HDE for the Activa Therapy System remained appropriately approved for pediatric use. In 2018, the Activa deep brain stimulation system received FDA approval with an expanded indication as an adjunctive therapy for epilepsy.

The Brio Neuromodulation System (St. Jude Medical) received FDA approval in June of 2015. The device is indicated for the following conditions: (1) bilateral stimulation of the STN as an adjunctive therapy to reduce some of the symptoms of advanced levodopa-responsive Parkinson's disease that are not adequately controlled by medications; and (2) unilateral or bilateral stimulation of the VIM thalamus for the suppression of disabling upper extremity tremor in adult essential tremor individuals whose tremor is not adequately controlled by medications and where the tremor constitutes a significant functional disability. The Brio device differs from the Activa system in that it uses a constant current of electricity to the brain to provide stimulation, while Activa uses constant voltage. Per the FDA Summary of Safety and Effectiveness Data, the data supporting its use come from two clinical trials of the device, one in 136 Parkinson's disease individuals and the other in 127 individuals with essential tremor. In both studies, symptoms were not adequately controlled with medication. The system was used as an adjunct to medication for the patients with Parkinson's, while "the majority of patients with essential tremor who used the device were able to control their symptoms without the need for medications," the FDA said. All patients in the studies were implanted with the system; Parkinson's disease patients were evaluated at three months, and the essential tremor patients after six months of therapy. "Both groups showed statistically significant improvement on their primary effectiveness endpoint when the device was turned on compared to when it was turned off," the statement notes.

Published clinical trials have provided evidence to support the efficacy and safety of unilateral DBS of the VIM thalamus for essential tremor and for tremor of Parkinson's disease, and of bilateral DBS of the STN or GPi for advanced Parkinson's disease. In studies of unilateral thalamic DBS, tremor suppression was either total or clinically significant in 82-91% of patients who underwent implantation. Results were durable, and side effects were minimal. An additional benefit of DBS is that recurrence of tremor may be managed by changes in stimulation parameters. Although long-term data are minimal, studies have demonstrated that bilateral stimulation of the STN or GPi results in improvements of neurologic function. Case series investigating the use of DBS for the treatment of dystonia found that patients with primary dystonia experienced significant improvement in movement and in ADLs, but those patients with secondary dystonia experienced little improvement.

Medical Policy: Deep Brain Stimulation Policy Number: 7.01.23 Page: 9 of 16

Directional DBS

The St. Jude Medical Infinity DBS System is the first FDA-approved system to feature a directional lead, designed to deliver electrical current to a specific target in the brain and, thereby, minimize unwanted side effects from brain stimulation to non-targeted areas. On September 19, 2016, this St. Jude DBS system was approved by the FDA as a supplement to an earlier Premarket Approval (PMA) for the St. Jude Medical Brio Neurostimulation System. This approval was for a change in design, components, specifications, and material. According to the manufacturer, the Infinity DBS system is indicated for:

...bilateral stimulation of the subthalamic nucleus (STN) as an adjunctive therapy to reduce some of the symptoms of advanced levodopa-responsive Parkinson's disease that are not adequately controlled by medications, and unilateral or bilateral stimulation of the ventral intermediate nucleus (VIM) of the thalamus for the suppression of disabling upper extremity tremor in adult essential tremor individuals whose tremor is not adequately controlled by medications and where the tremor constitutes a significant functional disability.

The St. Jude Medical Infinity DBS System, 8 Channel Directional Leads was recalled in 2018 due to a manufacturing issue; however, the recall was terminated in September 2020.

In January 2020, Abbott received approval from the FDA for a new, expanded indication for the Infinity Deep Brain Stimulation (DBS) system to include targeting of an area of the brain called the internal globus pallidus (GPi) which plays an integral role in the motor function and can be targeted with DBS to improve the symptoms of Parkinson's disease not adequately controlled by medication. The Abbott Infinity DBS system with directional leads provides directed stimulation to areas of the brain to optimize individual outcomes and limit side effects.

The Vercise PC Deep Brain Stimulation (DBS) System and the Vercise Gevia Deep Brain Stimulation (DBS) System (Boston Scientific, Inc.) were originally FDA approved on January 10, 2019. The Vercise Genus DBS System was FDA approved on January 21, 2021. These systems are indicated for use in the following: 1) bilateral stimulation of the subthalamic nucleus (STN) as an adjunctive therapy in reducing some of the symptoms of moderate to advanced levodopa-responsive Parkinson's disease (PD) that are not adequately controlled with medication; 2) bilateral stimulation of the globus pallidus internus (GPi) as an adjunctive therapy in reducing some of the symptoms of advanced levodopa responsive Parkinson's disease (PD) that are not adequately controlled with medication; 3) unilateral thalamic stimulation of the ventral intermediate nucleus (VIM) is indicated for the suppression of tremor in the upper extremity for which the system is intended for use in individuals who are diagnosed with essential tremor or parkinsonian tremor not adequately controlled by medications and where the tremor constitutes a significant functional disability. The Vercise DBS system utilizes current steering across eight contacts per DBS lead, which is intended to provide precise positioning of stimulation.

Medical Policy: Deep Brain Stimulation Policy Number: 7.01.23 Page: 10 of 16

Obsessive Compulsive Disorder (OCD)

In February of 2009, the FDA granted HDE approval to Medtronic's ReClaim Deep Brain Stimulator device as the first implant to treat OCD. The device is indicated for bilateral stimulation of the anterior limb of the internal capsule (AIC), as an adjunct to medications and as an alternative to anterior capsulotomy for the treatment of chronic, severe, treatment-resistant OCD in adult individuals who have failed at least three selective serotonin reuptake inhibitors (SSRIs). The HDE approval was based on a review of data from 26 individuals with severe, treatment-resistant OCD who were treated with the device at four sites. On average, individuals had a 40 percent reduction in their symptoms after 12 months of therapy. One of the major limitations of this study was the fact that many of the study population were aware of when the device was turned on and off, so investigators were unable to rule out that some of the improvements were due to a placebo effect. According to their consensus guidelines published in 2021, the World Society for Stereotactic and Functional Neurosurgery considers DBS to be an emerging but not yet established treatment for OCD. While there is limited evidence to suggest that DBS may be an option for individuals with severe, disabling OCD, well-designed large group studies are necessary to demonstrate its long-term safety and efficacy.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
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	each additional array
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	each additional array
61880	Revision or removal of intracranial neurostimulator electrodes

Medical Policy: Deep Brain Stimulation Policy Number: 7.01.23 Page: 11 of 16

Code	Description
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
61886	with connection to two or more electrode arrays
61888	Revision or removal of cranial neurostimulator pulse generator or receiver
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact groups[s], interleaving, amplitude, pulse width, frequency [HZ], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional
95984	each additional 15 minutes face-to-face time with physician or other qualified health care professional (list separately in addition to code for primary procedure)

Copyright © 2025 American Medical Association, Chicago, IL

HCPCS Codes

Code	Description
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1787	Patient programmer; neurostimulator
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency with rechargeable battery and charging system
L8679	Implantable neurostimulator pulse generator, any type

Medical Policy: Deep Brain Stimulation Policy Number: 7.01.23 Page: 12 of 16

Code	Description
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
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
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only

ICD10 Codes

Code	Description
G20.A1-G20.C	Parkinson's disease (code range)
G21.11-G21.9	Secondary Parkinsonism (code range)
G24.1-G24.3	Dystonia (code range)
G24.8	Other dystonia
G24.9	Dystonia, unspecified
G25.0	Essential tremor
G40.0-G40.919	Epilepsy and recurrent seizures (intractable) (code range)
Investigational Codes:	
All other ICD10 diagnosis codes are considered investigational.	

Medical Policy: Deep Brain Stimulation Policy Number: 7.01.23 Page: 13 of 16

REFERENCES

American Academy of Neurology [Internet] Update: treatment of essential tremors practice guidelines. Oct 2011. [updated 2022 Jul 16; accessed 2025 Mar 14]. Available from: https://www.aan.com/Guidelines/home/GuidelineDetail/925

Cruz S, et al. Deep brain stimulation in obsessive-compulsive disorder: results from meta-analysis. Psychiatry Research. 2022;317:114869.

Fisher R, et al. Electrical stimulation of the anterior nucleus of the thalamus for treatment of refractory epilepsy. Epilepsia. 2010 May 5;51(5):899-908.

Hariz MI, et al. Multicentre European study of thalamic stimulation for Parkinsonian tremor: a 6 year follow-up. J Neurol Neurosurg Psychiatry. 2008 Jun;79(6):694-9.

Herrman H, et al. Anterior thalamic deep brain stimulation in refractory epilepsy: A randomized, double-blinded study. Acta Neurol Scand. 2019 Mar;139(3):294-304.

Jost ST, et al. International Parkinson and Movement Disorders Society Non-Motor Parkinson's Disease Study Group and EUROPAR. neurostimulation for advanced Parkinson disease and quality of life at 5 Years: A nonrandomized controlled trial. JAMA Netw Open. 2024 Jan 2;7(1):e2352177.

Krauss JK, et al. Technology of deep brain stimulation: current status and future directions. Nat Rev Neurol. 2021 Feb;17(2):75-87.

Kumar KK, et al. Comparative effectiveness of neuroablation and deep brain stimulation for treatment-resistant obsessive-compulsive disorder: a meta-analytic study. J Neurol Neurosurg Psychiatry. 2019 Apr;90(4):469-473.

National Institute for Health and Clinical Excellence [Internet]. Deep brain stimulation for tremor and dystonia (excluding Parkinson's disease). IPG188. 2006 Aug [accessed 2025 Mar 13]. Available from: https://www.nice.org.uk/guidance/ipg188

National Institute for Health and Clinical Excellence [Internet]. Deep brain stimulation for Parkinson's disease. IPG19. 2003 Nov [accessed 2025 Mar 13]. Available from: https://www.nice.org.uk/guidance/ipg19

National Institute for Health and Clinical Excellence [Internet]. Deep brain stimulation for intractable trigeminal automatic cephalalgias. IPG381. 2011 Mar [accessed 2025 Mar 13]. Available from: https://www.nice.org.uk/guidance/ipg381

National Institute for Health and Clinical Excellence [Internet]. Deep brain stimulation for refractory chronic pain syndromes. IPG382. 2011 Mar [accessed 2025 Mar 13]. Available from: https://www.nice.org.uk/guidance/ipg382

National Institute for Health and Clinical Excellence [Internet]. Deep brain stimulation for refractory epilepsy in adults. IPG678. 2020 Aug 12 [accessed 2025 Mar 13].

Medical Policy: Deep Brain Stimulation Policy Number: 7.01.23 Page: 14 of 16

Ravindran K, et al. Deep brain stimulation versus peripheral denervation for cervical dystonia: a systematic review and meta-analysis. World Neurosurg. 2019 Feb;122:e940-e946.

Rodriguez-Oroz MC, et al. Efficacy of deep brain stimulation of the subthalamic nucleus in Parkinson's disease 4 years after surgery: double blind and open label evaluation. J Neurol Neurosurg Psych. 2004 Oct;75(10):1382-5.

Rodriquez-Oroz MC, et al. Bilateral deep brain stimulation in Parkinson's disease: a multicentre study with 4 years follow-up. Brain. 2005 Oct;128(pt 10):2240-9.

Rodrigues FB, et al. Deep brain stimulation for dystonia. Cochrane Database Syst Rev. 2019 Jan 10;1:CD012405.

Rodrigues JP, et al. Globus pallidus stimulation in advanced Parkinson's disease. J Clin Neurosci. 2007 Mar;14(3):208-15.

Salanova V, et al. The SANTÉ study at 10 years of follow-up: effectiveness, safety, and sudden unexpected death in epilepsy. Epilepsia. 2021;62(6):1306-17.

Schlaepfer TE, et al. Deep brain stimulation for treatment of refractory depression. Lancet. 2005 Oct 22-28;366(9495):1420-2.

Schnitzler A, et al. Directional deep brain stimulation for Parkinson's Disease: results of an international crossover study with randomized, double-blind primary endpoint. Neuromodulation. 2022;25:817-828.

Schupbach WM, et al. Neurosurgery at an earlier stage of Parkinson disease: a randomized, controlled trial. Neurol. 2007 Jan 23;68(4):267-71.

Schuurman PR, et al. A comparison of continuous thalamic stimulation and thalamotomy for suppression of severe tremor. NEJM. 2000 Feb 17;342(7):505-8.

Sharma A, et al. Efficacy and safety of deep brain stimulation as an adjunct to pharmacotherapy for the treatment of Parkinson disease. Ann Pharmacother. 2012 Feb;46(2):248-54.

Staudt MD, et al. Congress of Neurological Surgeons systematic review and evidence-based guidelines for deep brain stimulation for obsessive-compulsive disorder: update of the 2014 guidelines. Neurosurgery. 2021; 88(4):710-712.

Tir M, et al. Exhaustive, one-year follow-up of subthalamic nucleus deep brain stimulation in a large, single-center cohort of Parkinsonian patients. Neurosurg. 2007 Aug;61(2):297-304.

U. S. Food and Drug Administration [Internet]. Brio neuromodulation system. Summary of safety and effectiveness data. [updated 2015 Jun 12;accessed 2025 Mar 13]. Available from: http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140009b.pdf

U. S. Food and Drug Administration [Internet]. Vercise Deep Brain Stimulation System. Summary of safety and effectiveness data [updated 2017 Dec 08; accessed 2025 Mar 13]. Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150031B.pdf

Medical Policy: Deep Brain Stimulation Policy Number: 7.01.23 Page: 15 of 16

U. S. Food and Drug Administration [Internet]. Medtronic DBS System for Epilepsy. Summary of safety and effectiveness data [updated 2010 Mar 12; accessed 2025 Mar 13]. Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf/P960009S219B.pdf

Visser-Vanderwalle V, et al. Long-term effects of bilateral subthalmic nucleus stimulation in advanced Parkinson disease: a four-year follow-up study. Parkinsonism Relat Disord. 2005 May;113(3):157-65.

Volkmann J, et al. Pallidal deep brain stimulation in patients with primary generalized or segmental dystonia: a 5-year follow-up of a randomized trial. Lancet Neurol. 2012 Dec;11(12):1029-38.

Welter ML, et al. Internal pallidal and thalamic stimulation in patients with Tourette's syndrome. Arch Neurol. 2008 Jul;65(7):952-7.

Williams A, et al. Deep brain stimulation plus best medical therapy versus best medical therapy alone for advanced Parkinson's disease (PD SURG trial): a randomized, open-label trial. Lancet Neurol. 2010 Jun;9(6):581-91.

Zesiewicz TA, et al. Practice parameter: therapies for essential tremor: report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurol. 2005 Jun 28;64(12):2008-20.

Zesiewicz TA, et al. Evidence-based guideline update: treatment of essential tremor: report of the Quality Standards subcommittee of the American Academy of neurology. Neurology. 2011 Nov 8;77(19):1752-5.

Zong H, et al. Clinical study of the effects of deep brain stimulation on urinary dysfunctions in patients with Parkinson's disease. Clin Interv Aging. 2019 Jun 25;14:1159-1166.

Zorzi G, et al. Stimulation of the globus pallidus internus for childhood-onset dystonia. Mov Disord. 2005 Sep;20(9):1194-200.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Deep Brain Stimulation (NCD 160.24) [accessed 2025 Mar 13]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.

Medical Policy: Deep Brain Stimulation Policy Number: 7.01.23 Page: 16 of 16

- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

09/16/99, 07/19/01, 05/16/02, 03/20/03, 03/18/04, 03/17/05, 01/19/06, 01/18/07, 11/15/07, 11/20/08, 10/29/09, 10/28/10, 09/15/11, 08/16/12, 07/18/13, 06/19/14, 05/29/15, 06/16/16, 05/18/17, 04/19/18, 03/21/19, 02/20/20, 02/18/21, 02/17/22, 04/20/23, 04/18/24, 04/17/25

Date	Summary of Changes	
04/17/25	Annual review. Policy intent unchanged.	
01/01/25	Summary of changes tracking implemented.	
09/16/99	Original effective date	