MEDICAL POLICY

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MEDICAL POLICY DETAILS	
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Category	**Technology Assessment**
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Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), 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.* • *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 STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, conventional unilateral or bilateral deep brain stimulation of the ventral intermediate nucleus (VIM) thalamus has been medically proven to be effective and, therefore, is considered a **medically appropriate** treatment option in the management of disabling, medically unresponsive essential tremor or tremor due to Parkinson's disease (bilateral deep brain stimulation (DBS) would be utilized for bilateral tremor).

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 months before implant.

II. Based upon our criteria and assessment of the peer-reviewed literature, conventional unilateral or bilateral deep brain stimulation of the subthalamic nucleus (STN) or of the globus pallidus interna (GPi) has been medically proven to be effective and, therefore, is considered a **medically appropriate** treatment option in the management of advanced Parkinson's disease. **ALL** of the following criteria must be met:

A. The patient has a diagnosis of idiopathic (not secondary) Parkinson's disease; and
B. The patient's Parkinson's disease was previously responsive to levodopa therapy but is now medically intractable; and
C. The patient has severe levodopa-induced dyskinesia or disease characterized by severe bradykinesia, rigidity, tremor or dystonia, or by marked "on-off" fluctuations.

III. Based upon our criteria and assessment of the peer-reviewed literature, conventional bilateral deep brain stimulation of the STN or of the GPi has been medically proven to be effective and, therefore, is considered a **medically appropriate** treatment option in the management of patients who have had a Parkinson's diagnosis for at least four

years' duration and who have recently developed motor complications that cause significant limitations in daily activities (patient need not be considered as having advanced Parkinson's disease).

IV. Based upon our criteria and assessment of the peer-reviewed literature, conventional unilateral or bilateral deep brain stimulation of the STN or GPi has been medically proven to be effective and, therefore, is considered a **medically appropriate** treatment option in the management of patients seven years of age or older who experience chronic, intractable primary dystonia, including generalized and focal dystonia.

V. Based upon our criteria and assessment of the peer-reviewed literature, unilateral or bilateral deep brain stimulation of the anterior nucleus of the thalamus (ANT) is considered **medically appropriate** for individuals with a confirmed diagnosis of epilepsy and who have met **ALL** of the following criteria:

A. 18 years of age or older; and
B. Focal partial onset seizures with or without generalized seizure; and
C. Refractory to medical therapy defined as failure to adequately control seizures after two (or more) appropriate and adequately dosed anti-seizure medications or intolerance to anti-seizure medications; and
D. Currently having an average of three or more disabling seizures (for example, motor partial seizures, complex partial seizures, or secondary generalized seizures) per month over the most recent three months; and
E. Absence of progressive neurological conditions such as neurodegenerative disease.

VI. Based upon our criteria and assessment of the peer-reviewed literature, directional deep brain stimulation (e.g., St. Jude Medical Infinity DBS System and Vercise DBS System) has not been medically proven to be effective, and therefore, is considered **investigational** for all indications.

VII. Based upon our criteria and assessment of the peer-reviewed literature, conventional deep brain stimulation has not been medically proven to be effective and, therefore, is considered **investigational** for all conditions not specifically identified in Policy Statements I through V, including, but not limited to, the following conditions:

A. multiple sclerosis;
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; or
K. treatment-resistant obsessive-compulsive disorder.

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.

Refer to Corporate Medical Policy # 7.01.103 Responsive Neurostimulation for the Treatment of Refractory Focal Epilepsy.

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services.

POLICY GUIDELINES

I. Bilateral stimulators may be implanted simultaneously or in staged procedures.

II. Deep brain stimulation is contraindicated for some patients, including the following:

A. Patients who are not good surgical candidates because of unstable medical problems;
B. Patients who have a cardiac pacemaker;
C. Patients who have medical conditions that require repeated magnetic resonance imaging (MRI);

D. Patients who have dementia that may interfere with the ability to cooperate; and
E. Patients who have had botulinum toxin injections within the last six months.

III. Repair and/or replacement of a medically necessary DBS and/or components not under warranty will be considered **medically appropriate** when the following criteria are met:

A. Physician documentation includes **ALL** of the following:

1. date of device implantation/initiation,
2. manufacturer warranty information, and
3. attestation that the patient has been compliant with the use of device and will continue to benefit from the use of device; **AND ONE OF THE FOLLOWING APPLY**:

B. *Repair* of the currently used device, when **ALL** of the following are met:
1. it is no longer functioning adequately,
2. inadequate function interferes with activities of daily living, and
3. repair is expected to make the equipment fully functional (as defined by manufacturer); **OR**

C. *Replacement* of the currently used device, when the following are met:
1. it is no longer functioning adequately, **AND EITHER**
2. has been determined to be non-repairable, or
3. the cost of the repair is in excess of the replacement cost; **OR**

D. *Replacement* of the currently used device, when **BOTH** of the following are met:
1. there is documentation that a change in the patient's condition makes the present unit non- functional, and
2. improvement is expected with a replacement unit.

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 patient'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.

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.

RATIONALE

The U.S. Food and Drug Administration (FDA) has approved the Activa Tremor Control System (Medtronic, Inc.) for DBS. While 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 patients 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. The expanded approval is based on data from the EARLYSTIM clinical study (Schuepbach WM et al., 2013), which found that patients 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 patients treated with BMT alone. In a study of patients with longer-standing motor complications, DBS patients' quality of life improved 20 percent from baseline to six months, compared to no improvement in the patients 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 patients seven years of age or older.

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 patients 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 patients and the other in 127 patients 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.

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 patients whose tremor is not adequately controlled by medications and where the tremor constitutes a significant functional disability.

In December 2017, Boston Scientific, Inc. received PMA approval from the FDA for its Vercise Deep Brain Stimulation System, which includes directional lead technology. The Vercise DBS System is indicated for use in bilateral stimulation of the STN as an adjunctive therapy in reducing some of the symptoms of moderate-to-advanced, levodopa-responsive Parkinson's disease that are not adequately controlled with medication. The Vercise DBS system utilizes current steering across eight contacts per DBS lead, which is intended to provide precise positioning of stimulation.

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 patients who have failed at least three selective serotonin reuptake inhibitors (SSRIs). The HDE approval was based on a review of data from 26 patients with severe, treatment-resistant OCD who were treated with the device at four sites. On average, patients 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. While there is limited evidence to suggest that DBS may be an option for patients with severe, disabling OCD, well-designed studies are necessary to demonstrate its long-term safety and efficacy.

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 year (n=99), median change for seizure frequency from baseline decreased by 41% ($p<0.001$), and by 69% at five 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 year and 6.1 points at 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 or more seizures per month over the three 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.

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.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/appropriate = (NMN)*

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
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

Code	Description
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)

HCPCS Codes

Code	Description
C1767	Generator, neurostimulator (implantable), nonrechargeable
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
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	Parkinson's disease
G21.11-G21.9	Secondary Parkinsonism (code range)

Code	Description
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.	

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*Key Article

KEY WORDS

Brain stimulation, Parkinson's disease, Reclaim, Thalamus, Tremor, dystonia.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for deep brain stimulation. Please refer to the following NCD website for Medicare Members: [http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=279&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&CptHcpcsCode=36514&bc=gAAAABAAAAAA&].