MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**DEEP BRAIN STIMULATION**
Policy Number	**7.01.23**
Category	**Technology Assessment**
Effective Date	**10/18/01**
Revised Date	**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**
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 product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.* • *If a Medicare 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.*

POLICY STATEMENT

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

Disabling, medically unresponsive tremor is defined as both of the following:
A. tremor causes significant limitation in daily activities; and
B. inadequate control by maximal dosage of medication for at least 3 months before implant.

II. Based upon our criteria and assessment of the peer-reviewed literature, 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 **medically appropriate** for treatment 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;
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 peer-reviewed literature, 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 **medically appropriate** for treatment 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 peer-reviewed literature, unilateral or bilateral deep brain stimulation of the GPi or STN has been medically proven effective and therefore **medically appropriate** in patients 7 years of age or greater who experience chronic, intractable, primary dystonia, including generalized and focal dystonia.

V. Based upon our criteria and assessment of the peer-reviewed literature, there is insufficient clinical evidence to support the safety and efficacy of deep brain stimulation, and it is therefore considered **investigational** for the following conditions, including but not limited to:

A. Multiple Sclerosis,
B. post-traumatic dyskinesia;
C. all other movement disorders;
D. chronic pain syndromes, including cluster headache;
E. tardive dyskinesia;
F. epilepsy;
G. Tourette syndrome;
H. Dementias, including Alzheimer's disease;
I. Eating disorders, including Anorexia nervosa;
J. Alcohol addiction;
K. treatment-resistant depression; or
L. treatment-resistant obsessive compulsive disorder.

VI. **Contraindications** to deep brain stimulation include:
A. patients who are not good surgical risks because of unstable medical problems;
B. patients who have a cardiac pacemaker;
C. patients who have medical conditions that require repeated MRI; and
D. patients who have neuropsychiatric disease that may interfere with their ability to benefit from deep brain stimulation.

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.

This medical policy does not address stimulation of the motor cortex, which has been investigated as a treatment for patients with chronic, refractory neuropathic pain and extremity weakness due to stroke. In motor cortex stimulation, electrodes are implanted subdurally over the sensorimotor cortex.

POLICY GUIDELINES

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

II. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION

Deep brain stimulation (DBS) has been investigated as an alternative to permanent neuroablative 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. Deep brain stimulation 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 3 common target sites are the VIM thalamus, globulus pallidus interna and subthalamic nucleus. Whereas unilateral/bilateral DBS of the thalamus is utilized to treat essential tremor or tremors of advanced Parkinson's disease, bilateral deep brain stimulation of the subthalamic nucleus (STN) or of the globus pallidus interna (GPi) is used for treatment of the entire constellation of Parkinsonian symptoms (e.g., tremor, rigidity, and bradykinesia). Deep brain stimulation 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 and 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 GPi or STN requires a bilateral procedure.

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

Directional 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 can't steer the stimulation precisely. Directional DBS systems use novel lead designs with segmented, multi-contact electrodes that allow for the activation of individual electrode contacts and also allows the physician to specify the exact amount of current needed for every contact of the electrode. Through 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, dysarthia and cognitive or behavioral disturbances sometimes seen in conventional DBS.

RATIONALE

The FDA 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 PD 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 of 2003, the FDA gave Humanitarian Device Exemption (HDE) approval to the Activa Therapy system for the unilateral or bilateral stimulation of the internal GPi or STN 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 greater.

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 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 2) 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. The Brio device differs from the Activa system in how it provides stimulation to the brain- using a constant current of electricity to the brain versus constant voltage. Per the FDA Summary of Safety and Effectiveness Data: Data supporting its use come from two clinical trials of the device, one in 136 PD patients and the other in 127 patients with ET. 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; PD patients were evaluated at 3 months, and the ET patients after 6 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 deep brain stimulation of the VIM thalamus for essential tremor and for tremor of Parkinson's disease and of bilateral deep brain stimulation 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 GPi or STN 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 ADL's, 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 therefore, proposed to minimize unwanted side effects from brain stimulation to non-targeted areas. On September 19, 2016, the St. Jude Medical Infinity™ DBS system was FDA approved 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. The most recent supplemental approval pertaining to the Infinity neurostimulation system was issued on May 1, 2017, and was for a firmware update. 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 FDA approval (PMA) for its Vercise Deep Brain Stimulation System that includes directional lead technology. The Vercise Deep Brain Stimulation (DBS) System is indicated for use in 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. 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)

The FDA approved Medtronic's *ReClaim* Deep Brain Stimulator device as the first implant to treat severe obsessive-compulsive disorder under a Humanitarian Device Exemption (HDE) approval in February 2009. 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 obsessive compulsive disorder in adult patients who have failed at least three selective serotonin reuptake inhibitors (SSRIs). The approval of the human device exemption 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

On April 27, 2018, the FDA approved the Medtronic DBS System for Epilepsy for bilateral stimulation of the anterior nucleus of the thalamus (ANT) as an adjunctive therapy for reducing the frequency of seizures in individuals 18 years of age or older diagnosed with epilepsy characterized by partial-onset seizures, with or without secondary generalization, that are refractory to 3 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 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.

Results of Medtronic's SANTE trial (Fisher, et al. 2010) show promising outcomes on the adjunct use of deep brain stimulation of the anterior nucleus of the thalamus over placebo stimulation for patients suffering from severe, refractory, partial-onset seizures. 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 (6) months. Longer-term studies are needed to better define its safety, efficacy and the subset of patients who would benefit most from this treatment.

Herrman and colleagues (2019) examined the safety and effect of anterior thalamic nucleus deep brain stimulation (ANT-DBS) on seizure frequency in a single-center, prospective, randomized, double blinded study. This study design was kept similar to the SANTE study which was the first randomized, double-blinded DBS trial with bilateral implantation to the ANT. The study originally planned to include 40 patients, however the halfway interim analysis revealed several patients had an increased seizure frequency under active stimulation and there was no difference between patients with and without stimulation after the blinded period. Therefore, the inclusion of additional patients was stopped based on the invasive nature of the intervention, lack of significant improvement, and the possible worsening of some patients. The authors conclude there was no significant difference in seizure frequency after the blinded period between patients with or without stimulation.

Other Indications

Published clinical trials have not provided evidence to support the efficacy and safety of deep brain stimulation for conditions including, but not limited to, Multiple Sclerosis, post-traumatic dyskinesia, treatment-resistant depression, Alzheimer's disease, Tourette syndrome, or for bilateral deep brain stimulation of the VIM thalamus. Studies of deep brain stimulation for the treatment of chronic pain have not provided evidence that this 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.*

CPT Codes

Code	Description
61850	Twist drill or burr hole(s) for implantation of neurostimulator electrodes, cortical
61863	Twist drill, burr hole, craniotomy or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; first array
61864	each additional array
61867	Twist drill, burr hole, craniotomy or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; first array
61868	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
61888	revision or removal of cranial neurostimulator pulse generator or receiver

Code	Description
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, 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 (eg, 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 *(effective 01/01/2019)*
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) *(effective 01/01/2019)*

HCPCS Codes

Code	Description
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency with rechargeable battery and charging system
C1787	Patient programmer; neurostimulator
L8679	Implantable neurostimulator pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
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

Code	Description
L8689	External recharging system for battery (internal) for use with implantable neurostimulator

ICD10 Codes

Code	Description
G20	Parkinson's disease
G21.11-G21.9	Parkinsonism (code range)
G24.02-G24.3	Dystonia (code range)
G24.5	Blepharospasm
G24.8	Other dystonia
G25.0	Essential tremor
G25.1	Drug-induced tremor
G25.2	Other specified forms of tremor
G80.3	Athetoid cerebral palsy

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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&.