Deep Brain Stimulation
Clinical Coverage Criteria

Overview

Deep brain stimulation (DBS) consists of electrical stimulation of specific sites in the brain with implanted electrodes to reduce the symptoms of movement disorders such as Parkinson's disease and Essential Tremor. Targeted areas include the ventral intermediate nucleus of the thalamus, the internal globus pallidus and the subthalamic nucleus. Each of these brain regions has two halves which control movement on opposite sides of the body. Unilateral DBS has been proposed for use in patients when the symptoms are more severe on one side. Bilateral DBS has been proposed for the treatment of bilateral symptoms.

At the present time, there is one device that has been approved by the FDA for deep brain stimulation. The Medtronic Activa® originally received FDA premarket approval (PMA) on July 31, 1997 for unilateral implantation in the subthalamic thalamus for the suppression of tremor in the upper extremity in patients who are diagnosed with essential tremor or parkinsonian tremor not adequatedly controlled with medications and where the tremor constitutes a significant functional disability. To date, there have been 64 supplemental applications filed by Medtronic that represent changes to the device in one way or another.

On January 14, 2002, the device received FDA approval for the bilateral stimulation of the internal globus pallidus (gpi) or the subthalamic nucleus (stn) as an adjunctive therapy in reducing some of the symptoms of advanced, levodopa-responsive parkinson's disease that are not adequately controlled with medication...

On April 15, 2003, the FDA approved the Medtronic Activa® under the Humanitarian use Device exemption for unilateral or bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) to aid in the management of chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis) in patients seven years of age or above.

On February 19, 2009, the FDA approved the Medtronic Reclaim™ Deep Brain Stimulation for Obsessive Compulsive Disorder (OCD) under the Humanitarian Use Device Exemption. A search of the peer-reviewed published literature on April 27, 2009 identified several case series studies and one small 10-month randomized sham-controlled crossover study (Mallet et al., 2008). Mallet et al. conclude that stimulation of the subthalamic nucleus may lessen the severity of obsessivecompulsive symptoms and improve global functioning in patients with refractory, severe OCD. Serious adverse events occurred in 11 of the 17 patients in whom stimulators were implanted. The occurrence of severe adverse events, the small number of patients, and the short duration of the study highlight the risks of stimulation of the subthalamic nucleus and the need for larger studies with longer follow-up. In addition to assessment in a larger number of patients, a comparison with other stimulation targets and surgical procedures would be desirable, as would an evaluation of the long-term benefits of stimulation of the subthalamic nucleus in patients with OCD, notably with respect to their quality of life and their ability to function in social and work environments." (Mallet et al., 2008) Because of the small number of patients studied, the lack of long-term follow-up, and the number of side effects, Fallon Health (FH) considers deep brain stimulation for OCD experimental/investigational.

Definitions

Humanitarian Use Device A humanitarian use device is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the U.S. per year. A device manufacturer's research and development costs could exceed its market returns for diseases or conditions affecting small patient populations. The FDA, therefore, developed a regulation to provide an incentive for the development of devices for use in the treatment or diagnosis of diseases affecting these populations.

Humanitarian Device Exemption This FDA regulation provides for the submission of a humanitarian device exemption (HDE) application, which is similar in both form and content to a premarket approval (PMA) application, but is exempt from the effectiveness requirements of a PMA. An HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. The application, however, must contain sufficient information for FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. A list of FDA approved humanitarian use devices are available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/HDEInformation.cfm.

Obsessive Compulsive Disorder Obsessive-compulsive disorder (OCD) is a common psychiatric disease that is marked by recurring, anxiety-provoking thoughts (obsessions) accompanied by repetitive and time-consuming behaviors (compulsions). Currently, the standard of care for OCD management remains pharmacological in nature, often occurring in conjunction with cognitive behavioral therapy. Refractory cases, however, are occasionally referred for neurosurgical consultation, and several procedures have been examined.

Policy

Preauthorization by an FH Medical Director is required.

FH covers unilateral deep brain stimulation of the ventral intermediate (Vim)nucleus of the thalamus for suppression of tremor in the upper extremity in individuals age 18 and older when all of the following criteria are met:

1. Diagnosis of Essential Tremor based on postural or kinetic tremors of hand(s) without other neurologic signs, or diagnosis of idiopathic Parkinson's Disease (presence of at least two cardinal Parkinson's Disease features (tremor, rigidity, or bradykinesis) which is of a tremor-dominant form, AND
2. Marked disabling tremor of at least level 3 or 4 on the Fahn-Tolosa- Marin Clinical Tremor Rating Scale (or equivalent scale) in the extremity intended for treatment, causing significant limitation in daily activities despite optimal therapy, AND
3. Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.

For Fallon Senior Plan™ members only, FH covers unilateral or bilateral deep brain stimulation of the ventral intermediate (Vim) nucleus, in accordance with Centers for Medicare & Medicaid (CMS) guidelines, when all of the following criteria are met:

1. Diagnosis of Essential Tremor based on postural or kinetic tremors of hand(s) without other neurologic signs, or diagnosis of idiopathic Parkinson's Disease (presence of at least two cardinal Parkinson's Disease features (tremor, rigidity, or bradykinesis) which is of a tremor-dominant form, AND

2. Marked disabling tremor of at least level 3 or 4 on the Fahn-Tolosa- Marin Clinical Tremor Rating Scale (or equivalent scale) in the extremity intended for treatment, causing significant limitation in daily activities despite optimal therapy, AND
3. Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.

FH covers unilateral or bilateral deep brain stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) for individuals age 18 and older when all of the following criteria are met:

1. Diagnosis of Parkinson's Disease based on the presence of at least 2 cardinal Parkinson's Disease features (tremor, rigidity or bradykinesia), AND
2. Advanced idiopathic Parkinson's Disease as determined by the use of Hoehn and Yahr or Unified Parkinson's Disease Rating Scale (UPDRS) Part III Motor Subscale, AND
3. L-dopa responsive with clearly defined periods, AND
4. Persistent disabling Parkinson's symptoms or drug side effects (e.g., dyskinesias, motor fluctuations, or disabling ”off" periods) despite optimal medical therapy, AND
5. Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.

FH covers unilateral or bilateral deep brain stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) for individuals 7 years of age and older when all of the following conditions are met:

1. Diagnosis of intractable (drug refractory) primary dystonia, including generalized and segmental dystonia, hemidystonia and cervical dystonia (torticollis).

Ventral intermediate nucleus may be referred to as either VIN or Vim in the medical literature.

Although FH's Technology Assessment Committee has determined that deep brain stimulation for obstructive compulsive disorder is experimental/investigational, the Federal Employees Health Benefits Program (FEHBP) requires coverage for all FDA-approved drugs, devices or biological products. Therefore, deep brain stimulation for obstructive compulsive disorder is covered for FEHBP members if an FH Medical Director determines that the procedure is medically necessary. (FEHBP Carrier Letter No. 2001-27

Exclusions

1. Non-idiopathic Parkinson's Disease or Parkinson's Plus" syndromes.
2. Cognitive impairment, dementia or depression, which would be worsened by or would interfere with the patient's ability to benefit from deep brain stimulation.
3. Current psychosis, alcohol abuse or other drug abuse.
4. Structural lesions such as basal ganglionic stroke, tumor or vascular malformation as etiology of the movement disorder.
5. Previous movement disorder surgery within the affected basal ganglion.
6. Significant medical, surgical, neurologic or orthopedic co-morbidities contraindicating deep brain stimulation surgery or stimulation.
7. Deep brain stimulation for obsessive compulsive disorder.

Codes

Coding for deep brain stimulation consists of a series of CPT codes describing the various steps of the procedure, i.e., implantation of the electrodes, implantation of the pulse generator, intra-operative monitoring and programming of the electrodes, and postoperative neuro-programming. Patients may undergo several sessions of electronic analysis with or without programming to find the optimal programming parameters.

For bilateral stimulation via implantation of two cranial neurostimulator pulse generators, each connected to a single lead, add modifier -50 to either 81885 or 61886. For bilateral stimulation via implantation of one cranial neurostimulator pulse generator, connected to two leads, use 61886.

The following ICD-9 diagnosis codes represent the conditions for which deep brain stimulation may be covered:
The device codes (L8680, L8681, L8686 and L8688) are used by the entity that supplies the device to the plan member. For implanted devices, this is typically the facility. Surgically implanted devices are not subject to the plan member's durable medical equipment benefit limit.

Code type	Code	Description
CPT	61863	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; first array
	61864	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; each additional array
	61867	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; first array
	61868	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; each additional array
	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	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to two or more electrode arrays
	61888	Revision or removal of cranial neurostimulator pulse generator or receiver
	95961	Functional cortical and subcortical mapping by stimulation and/or recording of electrodes on brain surface, or of depth electrodes, to provoke seizures or identify vital brain structures; initial hour of physician attendance
	95962	Functional cortical and subcortical mapping by stimulation and/or recording of electrodes on brain surface, or of depth electrodes, to provoke seizures or identify vital brain structures; each additional hour of physician attendance (List separately in addition to code for primary procedure) (Use 95962 in conjunction with code 95961)
	95970	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve,

		autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
	95975	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex cranial neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, each additional 30 minutes after first hour
	95978	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex deep brain neurostimulator pulse generator/transmitter, with initial or subsequent programming, first hour
	95979	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); each additional 30 minutes after first hour
HCPCS	L8680	Implantable neurostimulator electrode, each
	L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator
	L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
	L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
ICD-9-CM	332.0	Paralysis agitans
	332.1	Secondary Parkinsonism
	333.1	Essential and other specified forms of tremor
	333.6	Genetic torsion dystonia
	333.71	Athetoid cerebral palsy
	333.72	Acute dystonia due to drugs
	333.79	Other acquired torsion dystonia
	333.83	Spasmodic torticollis
ICD-10-CM	G20	Parkinson's disease
	G21.4	Vascular parkinsonism
	G21.11	Neuroleptic induced parkinsonism
	G21.19	Other drug induced secondary parkinsonism
	G21.2	Secondary parkinsonism due to other external agents
	G21.3	Postencephalitic parkinsonism
	G21.8	Other secondary parkinsonism
	G21.9	Secondary parkinsonism, unspecified
	G25.0	Essential tremor
	G25.1	Drug-induced tremor
	G25.2	Other specified forms of tremor
	G24.1	Genetic torsion dystonia
	G80.3	Athetoid cerebral palsy
	G24.02	Drug induced acute dystonia
	G24.09	Other drug induced dystonia
	G24.2	Idiopathic nonfamilial dystonia
	G24.8	Other dystonia
	G24.9	Dystonia, unspecified

	G24.3	Spasmodic torticollis
	G24.4	Idiopathic orofacial dystonia

References

1. Centers for Medicare & Medicaid Services (CMS) National Coverage Determination for Deep Brain Stimulation for Essential Tremor and Parkinson's disease (160.24)
2. U. S. Food and Drug Administration (FDA) Medtronic Activa® Parkinson's Control Therapy P960009/S007, Summary of Safety and Effectiveness.
3. U. S. Food and Drug Administration. Medtronic Activa® Parkinson's Control Therapy P960009,
4. U. S. Food and Drug Administration. Medtronic Activa® Dystonia Therapy - H020007. Issued April 15, 2003..
5. Vadailhet, et al. Deep-Brain Stimulation for Generalized Dystonia. New England Journal of Medicine 2005 Feb 3; 352(5):459-67.
6. Medtronic. Medtronic Acltiva® Therapy: Important Safety Information.
7. Mallet Luc, Polosan M, Jaafari N, et al. Subthalamic Nucleus Stimulation in Severe Obsessive-Compulsive Disorder. *N Engl J Med* 2008;359(20):2121-34.
8. U.S. Food and Drug Administration. Reclaim™ Deep Brain Stimulation for Obsessive Compulsive Disorder (OCD) Therapy H050003. Issued February 19, 2009. Available at:
9. Kiss, ZHT, Doig-Beyaert K, Eliasziw M, et al. The Canadian Multicentre Study of Deep Brain Stimulation for Cervical Dystonia. *Brain* 2007;130:2879-86.
10. Hayes Directory. Deep Brain Stimulation for Treatment of Dystonia. October 11, 2004. © 2004 Winifred S. Hayes, Inc.
11. Hayes Update Search. Deep Brain Stimulation for Treatment of Dystonia. November 18, 2008. © 2008 Winifred S. Hayes, Inc.
12. Ponce FA, Lozano AM. Deep brain stimulation state of the art and novel stimulation targets. *Prog Brain Res.*2010;184:311-24.
13. Williams A, Gill S, et al. Deep brain stimulation plus best medical therapy versus best medical therapy alone for advanced Parkinson's disease (PD SURG trial): a randomised, open-label trial. *Lancet Neurol.* 2010 June; 9(6): 581–591.
14. Jiménez MC, Vingerhoets FJ. Tremor revisited: treatment of PD tremor. *Parkinsonism Relat Disord.* 2012 Jan;18 Suppl 1:S93-5.
15. Bronte-Stewart H, Taira T, et al. Inclusion and exclusion criteria for DBS in dystonia. *Mov Disord.* 2011 Jun;26 Suppl. 1:S5-16.
16. Jahanshahi M, Czernecki V, Zurowski AM. Neuropsychological, neuropsychiatric, and quality of life issues in DBS for dystonia. *Mov Disord.* 2011 Jun;26 Suppl 1:S63-78.
17. Starr PA, Bejjani P, et al. Stereotactic techniques and perioperative management of DBS in dystonia. *Mov Disord.*2011 Jun;26 Suppl 1:S23-30.
18. Yianni J, Green AL, Aziz TZ. Surgical treatment of dystonia. *Int Rev Neurobiol*. 2011;98:573-89

Policy History

Origination Date:	11/1/2000
Approval (s):	Benefits Committee: 01/2001 Technology Assessment Committee (TAC): 11/1/2000; 01/31/2006, 09/30/2009; 2/26/2014 ICD 10 CM codes mapped; 4/23/2014 correction due to ICD 10 CM implementation delay.

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If

there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans. For Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this policy.