



## DEEP BRAIN STIMULATION

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### 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 adequately 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.. The original PMA approval and links to all of the FDA-approved supplements is available at the FDA website:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/PMA.cfm?ID=7024>.

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 obsessive-compulsive 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, FCHP 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 FCHP Medical Director is required.**



**FCHP covers unilateral deep brain stimulation of the ventral intermediate (Vim)<sup>1</sup> 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 bradykinesia) 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, FCHP 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 bradykinesia) 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.

**FCHP 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 "on" 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

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<sup>1</sup> Ventral intermediate nucleus may be referred to as either VIN or Vim in the medical literature.



5. Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.

**FCHP 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).

### **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. <sup>2</sup>

### **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:

- 332.0 (Parkinson's disease)
- 332.1 Secondary Parkinsonism
- 333.1 Essential and other specified forms of tremor

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<sup>2</sup> Although FCHP'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 FCHP Medical Director determines that the procedure is medically necessary. (FEHBP Carrier Letter No. 2001-27).



- 333.6 Idiopathic torsion dystonia
- 333.7 Symptomatic torsion dystonia
- 333.83 Spasmodic torticollis

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.

Codes	Number	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
		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

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**Products to which this policy applies**

- ⊕ FCHP Direct & Select Care
- ⊕ Fallon Preferred Care (PPO)
- ⊕ Major Medical
- ⊕ MassHealth
- ⊕ Commonwealth Care
- ⊕ Companion Care
- ⊕ Fallon Senior Plan™

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**Committee Review Dates**

Technology Assessment Committee: 11/1/2000, 01/31/2006, 09/30/2009  
 Benefits Committee: 01/2001  
 Technology Assessment Subcommittee: 01/24/2006, 05/07/2009, 06/23/09



**IMPORTANT NOTE**

**Not all services are covered for all products or employer groups.** This medical policy expresses FCHP's determination of whether certain services or supplies are medically necessary, experimental or investigational or cosmetic. FCHP has reached these conclusions based upon the regulatory status of the technology and a review of clinical studies published in peer-reviewed medical literature. Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. Members and their providers need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and the plan of benefits, the provisions of the benefits plan will govern. However, applicable state mandates will 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. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this medical policy.