

Protocol

Deep Brain Stimulation

(70163)

Medical Benefit		Effective Date: 07/01/14	Next Review Date: 05/15
Preauthorization	No	Review Dates: 09/07, 11/08, 09/09, 09/10, 09/11, 07/12, 05/13, 05/14	

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

Deep brain stimulation (DBS) involves the stereotactic placement of an electrode into the brain (i.e., hypothalamus, thalamus, globus pallidus, or subthalamic nucleus). DBS is used as an alternative to permanent neuroablative procedures for control of essential tremor (ET) and Parkinson's disease (PD). DBS is also being evaluated for the treatment of a variety of other neurologic and psychiatric disorders, including epilepsy, dystonia, cluster headache, Tourette syndrome, depression, and obsessive-compulsive disorder (OCD).

Background

Deep brain stimulation (DBS) has been investigated as an alternative to permanent neuroablative procedures, such as thalamotomy and pallidotomy. The technique has been most thoroughly investigated as an alternative to thalamotomy for unilateral control of essential tremor (ET) and tremor associated with Parkinson's disease (PD). More recently, there has been research interest in the use of DBS of the globus pallidus or subthalamic nucleus as a treatment of other parkinsonian symptoms, such as rigidity, bradykinesia, or akinesia. Another common morbidity associated with PD is the occurrence of motor fluctuations, referred to as "on and off" phenomena, related to the maximum effectiveness of drugs (i.e., the "on" state) and the nadir response during drug troughs (i.e., the "off" state). In addition, levodopa, the most commonly used anti-Parkinson's drug, may be associated with disabling drug-induced dyskinesias. Therefore, the optimal pharmacologic treatment of PD may involve a balance between optimal effects on Parkinson's disease symptoms versus the appearance of drug-induced dyskinesias. The effect of DBS on both Parkinson's disease symptoms and drug-induced dyskinesias has also been studied.

DBS has also been investigated in patients with primary and secondary dystonia, defined as a neurologic movement disorder characterized by involuntary muscle contractions, which force certain parts of the body into abnormal, contorted, and painful movements or postures. Dystonia can be classified according to age of onset, bodily distribution of symptoms, and cause. Age of onset can occur during childhood or during adulthood. Dystonia can affect certain portions of the body (focal dystonia and multifocal dystonia) or the entire body (generalized dystonia). Torticollis is an example of a focal dystonia. Primary dystonia is defined when dystonia is the only symptom unassociated with other pathology. Treatment options for dystonia include oral or injectable medications (i.e., botulinum toxin) and destructive surgical or neurosurgical interventions (i.e., thalamotomies or pallidotomies) when conservative therapies fail. Secondary dystonia is a dystonia brought on by an inciting event, such as a stroke, trauma, or drugs. Tardive dystonia is a form of drug-induced secondary dystonia.

DBS has been investigated in patients with chronic cluster headaches. Cluster headaches occur as episodic attacks of severe pain lasting from 30 minutes to several hours. The pain is usually unilateral and localized to the

eye, temple, forehead, and side of the face. Autonomic symptoms that occur with cluster headaches include ipsilateral facial sweating, flushing, tearing, and rhinorrhea. Cluster headaches occur primarily in men and have been classified as vascular headaches that have been associated with high blood pressure, smoking, alcohol use, etc. However, the exact pathogenesis of cluster headaches is uncertain. Positron emission tomography (PET) scanning and magnetic resonance imaging (MRI) have shown the hypothalamic region may be important in the pathogenesis of cluster headaches. Alterations in hormonal/serotonergic function may also play a role. Treatment of cluster headaches includes pharmacologic interventions for acute episodes and prophylaxis, sphenopalatine ganglion (SPG) blockade, and surgical procedures such as percutaneous SPG radiofrequency rhizotomy and gamma knife radiosurgery of the trigeminal nerve.

The role of DBS in treatment of other treatment-resistant neurologic and psychiatric disorders, particularly Tourette syndrome, epilepsy, obsessive-compulsive disorder (OCD), and major depressive disorders, is also being investigated. Ablative procedures are irreversible and, though they have been refined, remain controversial treatments for intractable illness. Interest has shifted to neuromodulation through DBS of nodes or targets within neural circuits involved in these disorders. Currently, a variety of target areas are being studied.

DBS involves the stereotactic placement of an electrode into the brain (i.e., hypothalamus, thalamus, globus pallidus, or subthalamic nucleus). The electrode is initially attached to a temporary transcutaneous cable for short-term stimulation to validate treatment effectiveness. Several days later, the patient returns to surgery for permanent subcutaneous implantation of the cable and a radiofrequency-coupled or battery-powered programmable stimulator. The electrode is typically implanted unilaterally on the side corresponding to the most severe symptoms. However, the use of bilateral stimulation using two electrode arrays has also been investigated in patients with bilateral, severe symptoms. After implantation, noninvasive programming of the neurostimulator can be adjusted to the patient's symptoms. This feature may be important for patients with PD, whose disease may progress over time, requiring different neurostimulation parameters. Setting the optimal neurostimulation parameters may involve the balance between optimal symptom control and appearance of side effects of neurostimulation, such as dysarthria, disequilibrium, or involuntary movements.

Regulatory Status

The U.S. Food and Drug Administration (FDA) has approved the Activa® Tremor Control System, manufactured by Medtronic Corp, MN, for deep brain stimulation. 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 April 2003, the labeled indications were expanded to include "unilateral or bilateral stimulation of the internal globus pallidus or subthalamic nucleus 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." This latter indication received FDA approval through the Humanitarian Device Exemption process. The Activa Tremor Control System consists of the following components: the implantable pulse generator, the deep brain stimulator lead, an extension that connects the lead to the power source, a console programmer, a software cartridge to set electrical parameters for simulation, and a patient control magnet, which allows the patient to turn the pulse generator on and off, or change between high and low settings.

In February 2009, the FDA approved deep brain stimulation with the Reclaim® device (Medtronic, Inc.) via the Humanitarian Device Exemption (HDE) process for the treatment of severe obsessive-compulsive disorder (OCD).

Related Protocol

Spinal Cord Stimulation

Policy (Formerly Corporate Medical Guideline)

Unilateral deep brain stimulation of the thalamus may be considered **medically necessary** in patients with disabling, medically unresponsive tremor due to essential tremor or Parkinson's disease.

Unilateral or bilateral deep brain stimulation of the globus pallidus or subthalamic nucleus may be considered **medically necessary** in the following patients:

- Those with Parkinson's disease with ALL of the following:
 - a good response to levodopa; AND
 - a minimal score of 30 points on the motor portion of the Unified Parkinson Disease Rating Scale when the patient has been without medication for approximately 12 hours; AND
 - motor complications not controlled by pharmacologic therapy.
- Patients aged older than seven years with chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis).

Deep brain stimulation for other movement disorders, including but not limited to multiple sclerosis, post-traumatic dyskinesia, and tardive dyskinesia, is considered **investigational**.

Deep brain stimulation for the treatment of chronic cluster headaches is considered **investigational**.

Deep brain stimulation for the treatment of other psychiatric or neurologic disorders, including but not limited to Tourette syndrome, depression, obsessive-compulsive disorder, anorexia nervosa, alcohol addiction, chronic pain, and epilepsy, is considered **investigational**.

Policy Guideline

Disabling, medically unresponsive tremor is defined as all of the following:

- tremor causing significant limitation in daily activities
- inadequate control by maximal dosage of medication for at least three months before implant.

Contraindications to deep brain stimulation include:

- patients who are not good surgical risks because of unstable medical problems or because of the presence of a cardiac pacemaker
- patients who have medical conditions that require repeated magnetic resonance imaging (MRI)
- patients who have dementia that may interfere with the ability to cooperate
- patients who have had botulinum toxin injections within the last six months.

Medicare Advantage

Medicare Advantage will consider unilateral or bilateral thalamic ventralis intermedius nucleus (VIM) deep brain stimulation (DBS) **medically necessary** for the treatment of essential tremor (ET) and/or Parkinsonian tremor and unilateral or bilateral subthalamic nucleus (STN) or globus pallidus interna (GPi) DBS for the treatment of Parkinson's disease (PD) only under the following conditions:

1. The devices are (FDA) approved devices for DBS or devices used in accordance with FDA approved protocols governing Category B Investigational Device Exemption (IDE) DBS clinical trials.
2. For thalamic VIM DBS to be considered reasonable and necessary, members must meet all of the following criteria:

- a. Diagnosis of ET based on postural or kinetic tremors of hand(s) without other neurologic signs, or diagnosis of idiopathic PD (presence of at least two cardinal PD features [tremor, rigidity or bradykinesia]) which is of a tremor-dominant form.
 - b. Marked disabling tremor of at least level three or four 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 medical therapy.
 - c. Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.
3. For STN or GPi DBS to be considered reasonable and necessary, patients must meet all of the following criteria:
- a. Diagnosis of PD based on the presence of at least two cardinal PD features (tremor, rigidity or bradykinesia).
 - b. Advanced idiopathic PD as determined by the use of Hoehn and Yahr stage or Unified Parkinson's Disease Rating Scale (UPDRS) part III motor subscale.
 - c. L-dopa responsive with clearly defined "on" periods.
 - d. Persistent disabling Parkinson's symptoms or drug side effects (e.g., dyskinesias, motor fluctuations, or disabling "off" periods) despite optimal medical therapy.
 - e. Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.

DBS is **not medically necessary** and is not covered for ET or PD members with any of the following:

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 DBS.
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 DBS surgery or stimulation.

Members who undergo DBS implantation should not be exposed to diathermy (deep heat treatment including shortwave diathermy, microwave diathermy and ultrasound diathermy) or any type of MRI, which may adversely affect the DBS system or adversely affect the brain around the implanted electrodes.

DBS should be performed with extreme caution in members with cardiac pacemakers or other electronically controlled implants, which may adversely affect or be affected by the DBS system.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced

procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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