Important note
Even though this policy may indicate that a particular service or supply may be 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. You 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 your plan of benefits, the provisions of your 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 Senior Care members, this policy will apply unless Medicare policies extend coverage beyond this Medical Policy & Criteria Statement. Senior Care policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS’s Coverage Issues Manual can be found on the CMS website.

SERVICE: Deep brain stimulation

PRIOR AUTHORIZATION: Required.

POLICY: 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 may be approved when ALL of the following criteria are met:

1. Diagnosis of Essential Tremor based on postural or kinetic tremors of the 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 medical therapy, AND
3. Willingness and ability to cooperate during a conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.

For Medicare members only, unilateral or bilateral deep brain stimulation of the ventral intermediate (Vim) nucleus, in accordance with Centers for Medicare & Medicaid (CMS) guidelines, may be approved when all of the following criteria are met:

1. Diagnosis of Essential Tremor based on postural or kinetic tremors of the 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 medical therapy, AND
3. Willingness and ability to cooperate during a conscious operative procedure, as well as during

Unilateral or bilateral deep brain stimulation of the internal globus pallidus (GPI) or the subthalamic nucleus (STN) may be approved 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 two 2 cardinal Parkinson’s Disease features tremor, rigidity or bradykinesia AND
2. Presence of 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
5. Willingness and ability to cooperate during a conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.

Unilateral or bilateral deep brain stimulation of the internal globus pallidus (GP) or the subthalamic nucleus (STN) may be approved 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), AND
2. Dystonia is significant and interferes with at least one ADL.

Exclusions: Deep Brain Stimulation would be considered experimental or investigational and not covered for any other indication; including Obsessive Compulsive Disorder and Multiple Sclerosis.

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 is used in patients when the symptoms are more severe on one side. Bilateral DBS is used for treatment of bilateral symptoms.

At the present time, there are two devices that have 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 which interferes with one or more activities of daily living (ADL's). 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 as January 14, 2002. The original approval and links to all of the FDA-approved supplements to the Medtronic device are available at the FDA website:


Under the Humanitarian use Device exemption the FDA approved the Medtronic Activa® 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. (April 15, 2003)
The FDA approved the Medtronic Reclaim™ Deep Brain Stimulation device for Obsessive Compulsive Disorder (OCD) on February 19, 2009. The peer-reviewed published literature includes several case series studies and one small 10-month randomized sham-controlled crossover study supporting use of the device in OCD. Mallet et al. conclude (2008) 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.

MANDATES:  none

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 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.

Due to the wide range of applicable diagnosis codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

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<th>CPT codes:</th>
<th>61863, 61864, 61867, 61868, 61880, 61885, 61886, 61888, 95961, 95962, 95970, 95978, 95979</th>
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<td>HCPCS codes</td>
<td>L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688, L8689</td>
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| ICD9 codes:      | 332.0 - Parkinson's disease  
333.6 – Genetic torsion dystonia  
333.7 – Acquired torsion dystonia  
333.83 – Spasmodic torticollis   |
| ICD10 codes:     | G20: Parkinson's disease  
G24.1 - G24.9: Genetic torsion dystonia  
G24.2: Idiopathic nonfamilial dystonia  
G24.3: Spasmodic torticollis  
G24.8: Other dystonia  
G24.9: Dystonia, unspecified  
G25.0: Essential tremor  
G25.2: Other specified forms of tremor  
M43.6: Torticollis                  |
Deep Brain Stimulation

CMS: CMS issued a National Coverage Determination (NCD) on February 12, 2003 regarding Medicare coverage of DBS for the treatment of Essential Tremor and Parkinson’s Disease. The NCD states that, effective April 1, 2003, Medicare will cover unilateral or bilateral thalamic Vim DBS for the treatment of Essential Tremor and/or Parkinsonian tremor and unilateral or bilateral STN or GPi DBS for the treatment of Parkinson’s Disease only under the following conditions:

- DBS devices must be FDA-approved devices for DBS or devices used in accordance with FDA-approved protocols governing Category B Investigational Device Exemption (IDE) DBS clinical trials.

For thalamic Vim DBS to be considered reasonable and necessary, patients must meet all of the following criteria:

- Diagnosis of Essential Tremor based on postural or kinetic tremors of the hand(s) without other neurologic signs, or diagnosis of idiopathic Parkinson’s Disease P, defined as the presence of at least two cardinal Parkinson’s Disease features (tremor, rigidity, or bradykinesia), which is of a tremor-dominant form.
- 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 medical therapy.
- Willingness and ability to cooperate during a conscious operative procedure, as well as during postsurgical evaluations, adjustments of medications, and stimulator settings.

For STN or GPi DBS to be considered reasonable and necessary, patients must meet all of the following criteria:

- Diagnosis of Parkinson’s Disease based on the presence of at least two cardinal Parkinson’s Disease features (tremor, rigidity, or bradykinesia).
- Advanced idiopathic Parkinson’s Disease as determined by the use of Hoehn and Yahr stage or Unified Parkinson’s Disease Rating Scale (UPDRS) part III motor subscale.
- Levodopa responsive with clearly defined “on” periods.
- Persistent disabling Parkinson’s symptoms or drug side effects (e.g., dyskinesias, motor fluctuations, or disabling “off” periods) despite optimal medical therapy.
- Willingness and ability to cooperate during a conscious operative procedure, as well as during postsurgical evaluations, adjustments of medications and stimulator settings.

CMS does NOT consider DBS as reasonable and necessary and will not cover DBS for Essential Tremor or Parkinson’s Disease patients with any of the following:

- Nonidiopathic Parkinson’s disease or “Parkinson’s Plus” syndromes.
- Cognitive impairment, dementia, or depression that would be worsened by or would interfere with the patient’s ability to benefit from DBS.
- Current psychosis, alcohol abuse, or other drug abuse.
- Structural lesions such as basal ganglionic stroke, tumor, or vascular malformation as etiology of the movement disorder.
- Previous movement disorder surgery within the affected basal ganglion.
- Significant medical, surgical, neurologic, or orthopedic comorbidities contraindicating DBS surgery or stimulation.
MEDICAL COVERAGE POLICY
SERVICE: Deep Brain Stimulation
Policy Number: 025
Effective Date: 12/02/2013
Last Review: 11/14/2013
Next Review Date: 11/14/2014

POLICY HISTORY:

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REFERENCES:
The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.