**Protocol**

**Deep Brain Stimulation**

Medical Benefit  
**Effective Date:** 07/01/18  
**Next Review Date:** 05/23

<table>
<thead>
<tr>
<th>Preauthorization</th>
<th>Review Dates: 09/07, 11/08, 09/09, 09/10, 09/11, 07/12, 05/13, 05/14, 05/15, 05/16, 05/17, 05/18, 05/19, 05/20, 05/21, 05/22</th>
</tr>
</thead>
</table>

**Preauthorization is not required.**

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. 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.

**RELATED PROTOCOL**

Vagus Nerve Stimulation

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<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
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| Individuals:  
• With essential tremor or tremor in Parkinson disease | Interventions of interest are:  
• Deep brain stimulation of the thalamus | Comparators of interest are:  
• Pharmacologic therapy  
• Permanent neuroablative procedure (e.g., thalamotomy, pallidotomy) | Relevant outcomes include:  
• Symptoms  
• Functional outcomes  
• Quality of life  
• Treatment-related morbidity |

| Individuals:  
• With symptoms associated with Parkinson disease | Interventions of interest are:  
• Deep brain stimulation of the globus pallidus interna or subthalamic nucleus | Comparators of interest are:  
• Pharmacologic therapy  
• Physical and speech therapy | Relevant outcomes include:  
• Symptoms  
• Functional outcomes  
• Quality of life  
• Treatment-related morbidity |

| Individuals:  
• With primary dystonia | Interventions of interest are:  
• Deep brain stimulation of the globus pallidus interna or subthalamic nucleus | Comparators of interest are:  
• Pharmacologic therapy  
• Permanent neuroablative procedure (e.g., thalamotomy, pallidotomy) | Relevant outcomes include:  
• Symptoms  
• Functional outcomes  
• Quality of life  
• Treatment-related morbidity |

| Individuals:  
• With tardive dyskinesia or tardive dystonia | Interventions of interest are:  
• Deep brain stimulation | Comparators of interest are:  
• Pharmacologic therapy | Relevant outcomes include:  
• Symptoms  
• Functional outcomes  
• Quality of life  
• Treatment-related morbidity |

| Individuals:  
• With drug-refractory epilepsy | Interventions of interest are:  
• Deep brain stimulation | Comparators of interest are:  
• Pharmacologic therapy  
• Vagus nerve stimulation | Relevant outcomes include:  
• Symptoms  
• Functional outcomes |
### Populations

<table>
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<tr>
<th>Interventions of interest are:</th>
<th>Comparators of interest are:</th>
<th>Relevant outcomes include:</th>
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<td><strong>Individuals:</strong> With multiple sclerosis</td>
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<td><strong>Individuals:</strong> With Tourette syndrome</td>
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<td><strong>Individuals:</strong> With cluster headaches or facial pain</td>
<td>Deep brain stimulation</td>
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<tr>
<td><strong>Individuals:</strong> With treatment-resistant depression</td>
<td>Deep brain stimulation</td>
<td>Pharmacologic therapy, Behavioral therapy, Psychotherapy</td>
</tr>
<tr>
<td><strong>Individuals:</strong> With obsessive-compulsive disorder</td>
<td>Deep brain stimulation</td>
<td>Pharmacologic therapy, Behavioral therapy, Psychotherapy</td>
</tr>
<tr>
<td><strong>Individuals:</strong> With anorexia nervosa, alcohol addiction, Alzheimer disease, Huntington disease, or chronic pain</td>
<td>Deep brain stimulation</td>
<td>Pharmacologic therapy, Behavioral therapy, Psychotherapy</td>
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### DESCRIPTION

Deep brain stimulation involves the stereotactic placement of an electrode into a central nervous system nucleus (e.g., hypothalamus, thalamus, globus pallidus, subthalamic nucleus). Deep brain stimulation is used as an alternative to permanent neuroablative procedures for control of essential tremor and Parkinson disease. Deep brain stimulation is also being evaluated for the treatment of a variety of other neurologic and psychiatric disorders.
SUMMARY OF EVIDENCE

For individuals who have essential tremor or tremor in Parkinson disease who receive deep brain stimulation of the thalamus, the evidence includes a systematic review and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The systematic review (a TEC Assessment) concluded that there was sufficient evidence that deep brain stimulation of the thalamus results in clinically significant tremor suppression and that outcomes after deep brain stimulation were at least as good as thalamotomy. Subsequent studies reporting long-term follow-up have supported the conclusions of the TEC Assessment and found that tremors were effectively controlled 5 to 6 years after deep brain stimulation. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have symptoms (e.g., speech, motor fluctuations) associated with Parkinson disease (advanced or >4 years in duration with early motor symptoms) who receive deep brain stimulation of the globus pallidus interna or subthalamic nucleus, the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. One of the systematic reviews (a TEC Assessment) concluded that studies evaluating deep brain stimulation of the globus pallidus interna or subthalamic nucleus have consistently demonstrated clinically significant improvements in outcomes (e.g., neurologic function). Other systematic reviews have also found significantly better outcomes after deep brain stimulation than after a control intervention. An RCT in patients with levodopa-responsive Parkinson disease of at least 4 years in duration and uncontrolled motor symptoms found that quality of life at 2 years was significantly higher when deep brain stimulation was provided in addition to medical therapy. Meta-analyses of RCTs comparing deep brain stimulation of the globus pallidus interna with deep brain stimulation of the subthalamic nucleus have reported mixed findings and have not shown that 1 type of stimulation is superior to the other. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have primary dystonia who receive deep brain stimulation of the globus pallidus interna or subthalamic nucleus, the evidence includes systematic reviews, RCTs, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A pooled analysis of 24 studies, mainly uncontrolled, found improvements in motor scores and disability scores after 6 months and at last follow-up (mean, 32 months). Both double-blind RCTs found that severity scores improved more after active than after sham stimulation. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have tardive dyskinesia or tardive dystonia who receive deep brain stimulation, the evidence includes an RCT and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Few studies were identified and they had small sample sizes (range, 9-19 patients). The RCT did not report statistically significant improvement in the dystonia severity outcomes or the secondary outcomes related to disability and quality of life, but these may have been under-powered. Additional studies, especially RCTs or other controlled studies, are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have epilepsy who receive deep brain stimulation, the evidence includes systematic reviews, RCTs and many observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Two RCTs with more than 15 patients were identified. The larger RCT evaluated anterior thalamic nucleus deep brain stimulation and reported that deep brain stimulation had a positive impact on seizure frequency during some parts of the blinded trial phase, but not others, and a substantial number of adverse events (in >30% of patients). There were no differences between groups in 50% responder rates, Liverpool Seizure Severity Scale, or Quality of Life in Epilepsy scores. A 7-year open-label follow-up of the RCT included 66% of implanted patients; reasons for missing data were primarily related to adverse events or dissatisfaction with the device. Reduction in seizure frequency continued to improve during follow-up among the pa-
tients who continued follow-up. The smaller RCT (n=16) showed a benefit with deep brain stimulation. Many small observational studies reported fewer seizures compared with baseline, however, without control groups, interpretation of these results is limited. Additional trials are required to determine the impact of deep brain stimulation on patient outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have Tourette syndrome who receive deep brain stimulation, the evidence includes observational studies, RCTs, and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Two RCTs with 15 or more patients have been reported. One RCT found differences in severity of Tourette syndrome for active versus sham at 3 months, while the other RCT did not. Neither study demonstrated improvements in comorbid symptoms of obsessive-compulsive disorder or depression. Both studies reported high rates of serious adverse events. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have cluster headaches or facial pain who receive deep brain stimulation, the evidence includes a randomized crossover study and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. In the RCT, the between-group difference in response rates did not differ significantly between active and sham stimulation phases. Additional RCTs or controlled studies are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have treatment resistant depression who receive deep brain stimulation, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A number of case series and several prospective controlled trials evaluating deep brain stimulation have been published. Two RCTs of deep brain stimulation in the subgenual cingulate cortex and ventral striatum/ventral capsule were terminated for futility. Another RCT of stimulation of the same brain area (ventral striatum/ventral capsule) did not find a statistically significant difference between groups in the primary outcome (clinical response), and adverse psychiatric events occurred more frequently in the treatment group than in the control group. More recently, a controlled crossover trial randomized patients to sham or active stimulation of the anterior limb of the internal capsule after a year of open-label stimulation. There was a greater reduction in symptom scores after active stimulation, but only in patients who were responders in the open-label phase. Stimulation of the subcallosal (subgenual) cingulate was evaluated in a 2019 sham-controlled within-subject study that found prolonged response in 50% of patients and remission in 30% of patients with treatment resistant depression. Deep brain stimulation for patients with major depressive disorder who have failed all other treatment options is an active area of research, but the brain regions that might prove to be effective for treatment resistant depression have yet to be established. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have obsessive-compulsive disorder who receive deep brain stimulation, the evidence includes RCTs and meta-analyses. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Among the RCTs on deep brain stimulation for obsessive-compulsive disorder, only 1 has reported an outcome of clinical interest (therapeutic response rate), and that trial did not find a statistically significant benefit for deep brain stimulation compared with sham treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have multiple sclerosis who receive deep brain stimulation, the evidence includes an RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. One RCT with 10 multiple sclerosis patients is insufficient evidence on which to draw conclusions about the efficacy of deep brain stimulation in this population. Additional trials are required. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.
For individuals who have anorexia nervosa, alcohol addiction, Alzheimer disease, Huntington disease, or chronic pain who receive deep brain stimulation, the evidence includes case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. RCTs are needed to evaluate the efficacy of deep brain stimulation for these conditions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

**POLICY**

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 disease.

Bilateral deep brain stimulation of the thalamus may be considered **medically necessary** in patients with disabling, medically unresponsive tremor in both upper limbs due to essential tremor or Parkinson 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 disease and ALL of the following:
  - a good response to levodopa; AND
  - motor complications not controlled by pharmacologic therapy; AND
  - one of the following:
    - a minimum 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; OR
    - Parkinson disease for at least four years

- Patients 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 tardive dyskinesia, multiple sclerosis, and post-traumatic 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 epilepsy, Tourette syndrome, depression, obsessive-compulsive disorder, anorexia nervosa, alcohol addiction, Alzheimer disease, and chronic pain, is considered **investigational**.

**POLICY GUIDELINES**

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 DBS 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** 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.

**MEDICARE ADVANTAGE POLICY GUIDELINES**

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.

**BACKGROUND**

**DEEP BRAIN STIMULATION**

Deep brain stimulation 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 for permanent subcutaneous surgical 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, use of bilateral stimulation using 2 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 Parkinson disease, 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 adverse effects of neurostimulation, such as dysarthria, disequilibrium, or involuntary movements.

**REGULATORY STATUS**

In 1997, the Activa® Tremor Control System (Medtronic) was approved by the U.S. Food and Drug Administration (FDA) through the pre-market approval process for deep brain stimulation. The Activa Tremor Control System consists of an implantable neurostimulator, a 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 stimulation, and a patient control magnet, which allows the patient to turn the neurostimulator on and off or change between high and low settings.

The FDA labeled indications for Activa were originally limited to unilateral implantation for the treatment of tremor, but the indications have evolved over time. In 2002, the FDA labeled indications were expanded to include bilateral implantation as a treatment to decrease the symptoms of advanced Parkinson disease not controlled by medication. In 2003, the labeled indications were further 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 7 years of age or above.” In 2018, the deep brain stimulation system received an expanded indication as an adjunctive therapy for epilepsy (P960009-S219). Other deep brain stimulation systems are described in Table 1.
### Table 1. Deep Brain Stimulation Systems

<table>
<thead>
<tr>
<th>System</th>
<th>Manufacturer</th>
<th>FDA Product Code</th>
<th>PMA or HDE</th>
<th>Approval Date</th>
<th>Indications</th>
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<tbody>
<tr>
<td>Activa® Deep Brain Stimulation Therapy System</td>
<td>Medtronic</td>
<td>MBX</td>
<td>P96009</td>
<td>1997</td>
<td>Unilateral or bilateral stimulation of the internal globus pallidus or subthalamic nucleus for symptoms of Parkinson disease or primary dystonia</td>
</tr>
<tr>
<td>Reclalm® DBS Therapy for Obsessive Compulsive Disorder</td>
<td>Medtronic</td>
<td>H050003</td>
<td>2009</td>
<td></td>
<td>Bilateral stimulation of the anterior limb of the internal capsule for severe obsessive-compulsive disorder</td>
</tr>
<tr>
<td>Brio Neurostimulation System</td>
<td>St. Jude Medical</td>
<td>NHL</td>
<td>P140009</td>
<td>2015</td>
<td>Parkinsonian tremor (subthalamic nucleus) and essential tremor (thalamus)</td>
</tr>
<tr>
<td>Infinity DBS</td>
<td>Abbott Medical/St. Jude Medical</td>
<td>PJS</td>
<td>P140009</td>
<td>2016</td>
<td>Parkinsonian tremor</td>
</tr>
<tr>
<td>Vercise DBS System</td>
<td>Boston Scientific</td>
<td>NHL</td>
<td>P150031</td>
<td>2017</td>
<td>Moderate-to-advanced levodopa-responsive PD inadequately controlled with medication alone</td>
</tr>
<tr>
<td>Medtronic DBS System for Epilepsy</td>
<td>Medtronic</td>
<td>MBX</td>
<td>P96009-S219</td>
<td>2018</td>
<td>Expanded indication for epilepsy with bilateral stimulation of the anterior nucleus of the thalamus</td>
</tr>
<tr>
<td>Percept PC Deep Brain Stimulation</td>
<td>Medtronic</td>
<td>MHY</td>
<td>P96009-S</td>
<td>2020</td>
<td>Records brain signals while delivering therapy for PD or primary dystonia</td>
</tr>
<tr>
<td>Vercise Genus DBS System</td>
<td>Boston Scientific</td>
<td>NHL</td>
<td>P150031-S034</td>
<td>2021</td>
<td>Stimulation of the subthalamic nucleus and globus pallidus for PD</td>
</tr>
</tbody>
</table>

DBS: deep brain stimulation; HDE: humanitarian device exemption; OCD: obsessive-compulsive disorder; PD: Parkinson disease; PMA: premarket approval

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


