

Evidence Based Guideline

Deep Brain Stimulation

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Description of Procedure or Service

Deep brain stimulation 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 and tremor associated with Parkinson's disease (PD). More recently, there has been research interest in the use of deep brain stimulation 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 symptoms versus the appearance of drug-induced dyskinesias. The effect of deep brain stimulation (DBS) on both Parkinson's symptoms and drug-induced dyskinesias has also been studied.

DBS has also been investigated in patients with primary dystonia, defined as a neurological 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.

In addition, DBS has been recently 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.

DBS involves the stereotactic placement of an electrode into the brain (i.e., thalamus, globus pallidus, or subthalamic nucleus). The electrode is initially attached to a temporary transcutaneous cable for short-term

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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 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 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.

At the present time, only 1 device has been approved by the U.S. Food and Drug Administration (FDA) for deep brain stimulation: the Activa Tremor Control System, manufactured by Medtronic Corp, MN. 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 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.

*****Note: This Evidence Based Guideline is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

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- A. Unilateral deep brain stimulation of the thalamus may be appropriate in patients with disabling, medically unresponsive tremor due to essential tremor or Parkinson's disease when the following criteria are met:
 1. tremor causes significant limitation in daily activities, **and**
 2. there is inadequate control by maximal dosage of medication for at least 3 months before the implant.
- B. Unilateral or bilateral deep brain stimulation of the globus pallidus or subthalamic nucleus may be appropriate in patients with Parkinson's disease who meet all of the following:
 1. have a good response to levodopa; **and**
 2. have 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**
 3. have motor complications that are not controlled by pharmacologic therapy.
- C. Unilateral or bilateral deep brain stimulation of the globus pallidus or subthalamic nucleus may be appropriate in patients who are greater than 7 years old with chronic, intractable (drug **refractory**) primary dystonia, including generalized and/or segmental dystonia, hemidystonia and cervical dystonia (torticollis).

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Medical Evidence regarding Deep Brain Stimulation indicates it is not recommended in the following situations:

- A. For any indication that does not meet the above criteria.
- B. For other movement disorders, including but not limited to multiple sclerosis, post traumatic dyskinesia, and tardive dyskinesia.
- C. For the treatment of chronic cluster headaches.
- D. For the treatment of other psychiatric or neurologic disorders, including but not limited to Tourette syndrome, depression, obsessive compulsive disorder and epilepsy.
- E. When it is contraindicated:
 - 1. for patients who are not good surgical risks because of unstable medical problems;
 - 2. presence of a cardiac pacemaker;
 - 3. for patients who have medical conditions that require repeated magnetic resonance imaging (MRI);
 - 4. for patients who have dementia that may interfere with the ability to cooperate; or
 - 5. for patients who have had botulinum toxin injections within the last 6 months.

Deep brain stimulation has various steps to complete the procedure, which include implantation of the electrodes, implantation of the pulse generator, intraoperative monitoring and programming of the electrodes, and postoperative neuroprogramming. Over time, patients may undergo several sessions of electronic analysis and programming to find the optimal programming parameters.

No controlled trials of deep brain stimulation for seizures were identified in a recent literature search. A multi-center, randomized controlled trial of stimulation of the anterior nucleus of the thalamus in epilepsy (SANTE) is in progress. Two small crossover studies for deep brain stimulation for Tourette syndrome were identified, one comparing unilateral and bilateral stimulation (5 patients) and the other with 3 patients comparing thalamic, pallidal, simultaneous thalamic and pallidal, and sham stimulation. No controlled trials of deep brain stimulation for tardive dyskinesia or cluster headache were found.

A crossover double-blind, multicenter study of deep brain stimulation for the treatment of refractory obsessive-compulsive disorder (OCD) is reported by Mallet et al. The authors note that the multicenter design might be a limitation of the study because of variation in targeting of stimulation. In addition, in order to preserve blinding, stimulation settings were kept below the threshold to induce side effects and may have been too low to reduce symptoms. They conclude that their finding suggest that deep brain stimulation may lessen severity of symptoms, however serious adverse events did occur. Larger studies with longer follow-up are needed including evaluation of quality of life and ability to function in social and work situations.

Benefits Application

Please refer to certificate for availability of benefit. This guideline relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore certificate language should be reviewed before applying the terms of the policy.

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Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 61850, 61863, 61864, 61867, 61868, 61885, 61886, 95970, 95971, 95978, 95979, L8680, L8682, L8683, L8685, L8686, L8687, L8688, L8689

Medical Term Definitions

Refractory

not responding to treatment.

Stereotactic

precise positioning in three dimensional space; it may refer to surgery or radiation therapy that is directed by various scanning devices.

Subcutaneous

under the skin.

Thalamotomy

a surgical technique for the destruction of specific groups of cells within the thalamus, as for the relief of pain, tremor or rigidity in Parkinson's disease.

Scientific Background and Reference Sources

Medical Policy Reference Manual, issued 4/1/98

Medical Policy Reference Manual, issued 2/18/00

Specialty Matched Consultant Advisory Panel - 10/2000

Medical Policy Advisory Group - 10/2000

BCBSA TEC Evaluation 2001

BCBSA Medical Policy Reference Manual, 2/15/2002; 7.01.63

Unified Parkinson's Disease Rating Scale. http://www.wemove.org/par_rs.html; 4/17/2002

Specialty Matched Consultant Advisory Panel - 7/2002

Specialty Matched Consultant Advisory Panel - 7/2003

BCBSA Medical Policy Reference Manual [Electronic Version]. 4/1/2005.

Specialty Matched Consultant Advisory Panel - 6/2005

BCBSA Medical Policy Reference Manual [Electronic Version]. 3/7/2006

Specialty Matched Consultant Advisory Panel - 5/2007

BCBSA Medical Policy Reference Manual [Electronic Version]. 2/12/2009

Mallet L, Polosan M, Jaafari N et al. Subthalamic nucleus stimulation in severe obsessive-compulsive disorder. *N Engl J Med* 2008; 359(20):2121-34.

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Specialty Matched Consultant Advisory Panel - 5/2009

Policy Implementation/Update Information

- 9/98 Adopted BCBSA policy
- 7/99 Reformatted, Description of Procedure or Service changed, Medical Term Definitions added.
- 8/00 System coding changes.
- 9/00 Added statement saying, "Deep brain stimulation of locations other than the thalamus, including, but not limited to, the globus pallidus or subthalamic nucleus, is considered investigational." Also added additional information to the description section of the policy to improve clarity.
- 10/00 Specialty Matched Consultant Advisory Panel. No change recommended in criteria. Medical Policy Advisory Group review. No change in criteria. Approve.
- 12/00 2001 HCPCS coding added; E0756, E0757, E0758, E0765. System coding changes.
- 5/01 Policy key word added and format change.
- 5/02 Policy revised. Unilateral or bilateral deep brain stimulation of the globus pallidus or subthalamic nucleus may be considered medically necessary for patients who meet specific criteria as stated in the policy. Revised section for when it is not covered to remove statements that are no longer considered investigational. Format changes. Codes 61855, 61865, E0751, E0753 deleted and code E0752 added to Billing and Coding section.
- 8/02 Specialty Matched Consultant Advisory Panel review 7/12/2002. Revised under, when it is not covered section for clarity.
- 9/03 Specialty Matched Consultant Advisory Panel review 7/15/2003. No changes to criteria. Benefits Application section revised. Codes 61850, 61860, 61870, 61875, E0765 deleted and codes 61880, 61885, 61886, 61888, 95961, 95962, 95970, 95971, 95972, 95973 added to Billing/Coding section.
- 3/04 Billing/Coding section updated for consistency.
- 12/23/04 Code 95979 added to Billing/Coding section of policy.
- 7/7/05 Specialty Matched Consultant Advisory Panel review 6/24/2005. Changed policy name from "Deep Brain Stimulation of the Thalamus for Tremor" to "Deep Brain Stimulation". Revised "Description of Procedure or Service" section. Revised "Policy" section to remove specific reference to "of the thalamus for tremors". Revised the "When Covered" section and added "C. Unilateral or bilateral deep brain stimulation of the globus pallidus or subthalamic nucleus may be considered medically necessary in patients with Parkinson's disease who are greater than 7 years old with chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia and cervical dystonia (torticollis)." Removed codes; "61862, 61880, 61888, 95961, 95962, 95972, 95973, E0757, and E0758" as they are not specific to this policy. Added CPT codes; "61850, 61863, 61864, 61867, 61868, and 95978. References added.
- 1/6/05 Deleted HCPCS code E0752 and E0756 from "Billing/Coding" section.
- 8/28/06 Medical Policy changed to Evidence Based Guideline.
- 1/29/07 Removed statement under "When Covered" section "C. "with Parkinson's disease". Added HCPCS codes; L8680, L8682, L8683, L8685, L8686, L8687, L8688, and L8689 to "Billing/Coding" section.
- 6/18/07 Specialty Matched Consultant Advisory Panel review 5/23//2007. No changes to guideline. References added.

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8/31/09 Specialty Matched Consultant Advisory Panel review 5/28/09. "Description" section revised. Added "the motor portion of " to clarify the Unified Parkinson Disease Rating Scale statement in 2.B of the "Evidence Based Guideline" section. Under the "When Not Recommended" section added "tardive dyskinesia" to "B." and added "D. Deep Brain Stimulation is not recommended for the treatment of other psychiatric or neurologic disorders, including but not limited to Tourette syndrome, depression, obsessive compulsive disorder and epilepsy." Rationale added. References added. (btw)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.