

Evidence Based Guideline

Deep Brain Stimulation

File Name:	deep_brain_stimulation
Origination:	9/1998
Last CAP Review:	5/2011
Next CAP Review:	5/2012
Last Review:	8/2011

Description of Procedure or Service

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.

DBS requires 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. 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 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).

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*****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.**

Evidence Based Guideline for Deep Brain Stimulation

- 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) [Error! Reference source not found.](#) primary dystonia, including generalized and/or segmental dystonia, hemidystonia and cervical dystonia (torticollis).

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

- A.) For any indication that is not listed in the guideline above,.
- 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, seizures 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.

In 2010, Fisher et al. reported a U.S. multicenter, double-blind, randomized trial of bilateral stimulation of the anterior nuclei of the thalamus for epilepsy (SANTE). Although some patients appear to have benefited from treatment during the extended follow-up phase, the difference between groups in the blinded portion of the study was modest. Additional study is needed to establish the safety and efficacy of DBS for epilepsy.

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Benefits Application

This evidence based guideline relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this guideline.

Billing/Coding/Physician Documentation Information

This guideline 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

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.
Specialty Matched Consultant Advisory Panel - 5/2009
BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.63, 2/12/2009
Specialty Matched Consultant Advisory Panel - 5/2011
BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.63, 6/9/2011
Medical Director - 8/2011

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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.
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

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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)

- 6/22/10 Policy Guideline Number(s) removed (amw)
- 6/21/11 Specialty Matched Consultant Advisory Panel review 5/25/11. "Description" section updated. No change to "Evidence Based Guideline" References added. (btw)
- 8/30/11 "Description" section updated. No change to guideline intent. Reference added. Medical Director review 8/6/11. (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.