CLINICAL MEDICAL POLICY	
Policy Name:	Deep Brain Stimulation (DBS)
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Responsible Department(s):	Medical Management
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Products:	Highmark Health Options Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 12

DISCLAIMER

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under the medical surgical benefits of the Company's Medicaid products for deep brain stimulation (DBS).

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Limbic System
A system consisting of a set of brain structures that includes the hippocampus, amygdala, anterior thalamic nuclei, hypothalamus, and the limbic cortex. The limbic system functions are complex and

include the establishment of baseline emotional states, behavioral drives, facilitation of storage and retrieval of memories, and coordination and linkage of complex conscious functions of the cerebral cortex with the unconscious and autonomic function necessary for maintenance of homeostasis.

Depression
A mood or emotional disorder that causes a persistent feeling of low self-worth or guilt, sadness, and loss of interest. It is also called major depressive disorder or clinical depression. The exact cause of depression is not known. The course of the disorder is variable from person to person and may be classified as mild or severe, acute or chronic.

Deep Brain Stimulation (DBS)
A neurosurgical procedure to stereotactically implant electrodes unilaterally or bilaterally into a specific anatomic region within the brain. There are three targets for DBS: the thalamic ventralis intermedius nucleus (VIM), the subthalamic nucleus (STN), and the globus pallidus interna (GPi). The electrodes are connected to a subcutaneous implantable pulse generator that controls stimulation and provides the power source of the DBS system. Typically continuous electrical stimulation is provided.

Parkinson's disease
A progressive, incurable neurodegenerative disease caused by the slow continuous loss of nerve cells in the part of the brain that controls muscle movement.

Essential Tremor (ET)
A chronic, incurable condition without a known cause characterized by motor and nonmotor dysfunction. Motor dysfunction may be demonstrated by resting tremor, muscle rigidity, postural instability, and bradykinesia. Nonmotor dysfunction symptoms typically present earlier than signs of motor dysfunction and include sleep disorder, olfactory impairment, attention and/or memory impairment, apathy, depression, and anxiety. This disease is characterized by the degeneration of the dopaminergic system, which leads to the loss of dopamine neurons and dopamine function, causing movement and coordination dysfunction.

Primary Dystonia
A form of dystonia which is not due to a secondary cause such as stroke, cerebral palsy, tumor, trauma, infection, multiple sclerosis, medications, or a neurodegenerative disease.

Epilepsy
A neurological disorder that is characterized by recurrent seizures unprovoked by any immediate cause, when the brain's normal electrical activity becomes overactive and abnormal.

PROCEDURES

1. Medical Necessity Guidelines
   A. Essential Tremors (ET) and/or Parkinson Disease (PD) Tremor Using the Thalamic Ventralis Intermedius Nucleus (VIM) DBS
      1) The DBS device must be FDA approved and utilized according to the labeled indications; AND
      2) Treatment may be unilateral or bilateral; AND
      3) The patient has received appropriate screening and multidisciplinary evaluation; AND

4) The diagnosis of ET which is based on postural or kinetic tremors of hand(s) without other neurologic signs; OR
5) Diagnosis of idiopathic PD (presence of at least 2 cardinal PD features [tremor, rigidity or bradykinesia] that are of a tremor-dominant form); AND
6) 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
7) No focal lesion of the basal ganglia at the target site that would negate the result of the thalamic stimulation; AND
8) Patient willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.

B. Parkinson Disease Treatment with Subthalamic Nucleus (STN) or Globus Interna (GPi) DBS
1) The DBS device must be FDA approved and utilized according to the labeled indications; AND
2) Treatment may be unilateral or bilateral; AND
3) Diagnosis of PD for at least 4 years based on the presence of at least 2 cardinal PD features (tremor, rigidity, or bradykinesia); AND
4) Diagnosis of advanced idiopathic Parkinson's disease as determined by the use of Hoehn and Yahr stage or a minimal score of 30 points on the Unified Parkinson's Disease Rating Scale (UPDRS) part III motor subscale when off medication for 12 hours; AND
5) PD responsive to levodopa on clearly defined 'on' periods; AND
6) Persistent disabling PD symptoms or drug side effects (e.g., dyskinesias, motor fluctuations, or disabling 'off' periods) are present despite optimal medical therapy; AND
7) Patient willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.

Patient aged greater than 7 years with chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia and cervical dystonia (torticollis).

C. Drug Resistant Focal Epilepsy with Anterior Nucleus of the Thalamus DBS
1) Treatment is requested as a last resort; AND
2) The patient must be 18 years of age or older; AND
3) The patient has had diagnostic testing that localized no more than two epileptogenic foci; AND
4) The patient has partial onset seizures; AND
5) The patient's condition is refractory to three or more antiepileptic medications, as monotherapy or in combination; AND
6) The patient is currently experiencing an average of three or more disabling seizures (e.g., motor partial seizures, complex partial seizures, or secondary generalized seizures) per month for the past three months; AND
7) Treatment is bilateral

2. Contraindications
A. Patients who are not good surgical risks due to unstable medical issues; OR
B. Patients who have had previous movement disorder surgery in the affected basal ganglion; OR
C. Patients who are receiving electroconvulsive therapy and transcranial magnetic stimulation

3. Precautions
   A. Patients who have a cardiac pacemakers or other electronically controlled implants; AND
   B. Patients who have medical conditions that necessitate repeated MRIs; OR
   C. Patients who have neuropsychiatric disease that may interfere with their ability to benefit from DBS; OR
   D. The patient should not be diagnosed with extensive brain atrophy, cognitive impairment, dementia, or depression

4. When DBS Services Are Not Covered
   DBS is considered experimental/investigational for the treatment of any of the following, as there is insufficient evidence of effectiveness:
   A. Chronic pain syndrome
   B. Chronic cluster headache
   C. Headache
   D. Degenerative disorders
   E. Depression
   F. Head tremors, other tremor disorders (e.g., multiple sclerosis, CVA)
   G. Infectious disease
   H. Metabolic disorders
   I. Myasthenia Gravis
   J. Obsessive-compulsive disorder (OCD)
   K. Post trauma/surgical dystonia
   L. Tourette syndrome
   M. Vegetative state
   N. Voice tremors
   O. Non-idiopathic Parkinson's disease or Parkinson's Plus
   P. Huntington's disease
   Q. Alzheimer's disease
   R. Post-traumatic dyskinesia

5. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

6. Place of Service
   The place of service for deep brain stimulation is inpatient

GOVERNING BODIES APPROVAL

On February 19, 2009, the Reclaim™ Deep Brain Stimulation Therapy device was issued a Humanitarian Device Exemption (HDE) (H050003) for OCD for chronic, severe treatment-resistant OCD. The device is indicated for bilateral stimulation of the anterior limb of the internal capsule as an adjunct to medications and as an alternative to anterior capsulotomy for the treatment of chronic, severe, treatment-resistant OCD in adult patients who have failed at least three selective serotonin reuptake inhibitors (SSRIs).

Warnings: The following procedures are contraindicated for patients with DBS: diathermy (shortwave, microwave or therapeutic ultrasound diathermy) which can cause neurostimulation damage or tissue

damage and can result in severe injury or death; transcranial magnetic stimulation; certain MRI procedures using a full body transmit radio-frequency coil, a receive-only coil, or a head transmit coil that extends over the chest area.

The device may be affected by or adversely affect medical equipment such as cardiac pacemakers or therapies, cardioverter/defibrillators, external defibrillators, ultrasonic equipment, electrocautery, or radiation therapy.

On July 31, 2017, the FDA approved the Activa® Tremor Control System for unilateral thalamic stimulation for the suppression of tremor in the upper extremity that is the result of essential tremor or Parkinsonian tremor not adequately controlled by medications, and there is significant function disability.

The Activa® Parkinson's Control Therapy System was FDA approved in 2002 as a device for bilateral simulation of the internal globus pallidus or the subthalamic nucleus for adjunctive therapy in reducing some of the symptoms of advanced, levodopa-responsive Parkinson's disease that are not adequately controlled with medication. In November 2015, the FDA modified the approval for the treatment of Parkinson's disease to read, "bilateral stimulation of the internal globus pallidus or the subthalamic nucleus for Parkinson's disease is indicated for adjunctive therapy in reducing some of the symptoms in individuals with levodopa-responsive Parkinson's disease of at least 4 years' duration that are not adequately controlled with medication."

On June 12, 2015, the rechargeable Brio Neurostimulation System was approved by the FDA for the following indications:

- Bilateral stimulation of the subthalamic nucleus as an adjunctive therapy to reduce some of the symptoms of advanced levodopa-responsive Parkinson's disease that are not adequately controlled by medications;
- Unilateral or bilateral stimulation of the ventral intermediate nucleus of the thalamus for the suppression of disabling upper extremity tremor in adult essential tremor patients whose tremor is not adequately controlled by medications and where the tremor constitutes a significant functional disability.

In September 2016, the Infinity™ DBS System gained FDA approval as a directional lead that sends electrical impulses to an intended target instead of all directions as other DBS systems.

The Vercise™ Deep Brain Stimulation System was granted FDA approval in December 2017 for treatment of some symptoms of moderate to advanced levodopa-responsive Parkinson's disease which are not controlled by medication. This system uses bilateral stimulation of the subthalamic nucleus which is a selected target. The device was also approved for patients with intractable primary and secondary dystonia, for persons 7 years of age and older.

The Medtronic DBS System was FDA approved in April 2018 for the treatment of epilepsy. The device is for bilateral stimulation of the anterior nucleus of the thalamus (ANT) as an adjunctive treatment for reducing the frequency of seizures in individuals over the age of 18 or older who have been diagnosed with epilepsy that is described as partial-onset seizures, with or without secondary generalization, refractory to three or more antiepileptic medications.

There is no FDA approved device for the treatment of depression.

There are National Coverage Determinations (NCD) for DBS in the treatment of refractory epilepsy. There is an NCD for the use of DBS for the treatment of Essential Tremor and Parkinson's disease (NCD I60.24).

CODING REQUIREMENTS

Procedure Codes

CPT Codes	Description
61863	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; first array
61864	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; each additional array
61867	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recoding, first array
61868	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recoding, each additional array
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to single electrode array
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to two or more electrode arrays
HCPCS Code	**Description**
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

**These procedure codes will not be reimbursed without Medical Director approval.*

Diagnosis Codes

ICD-10 Codes	Description
G20	Parkinson's disease
G21.11	Neuroleptic induced parkinsonism
G21.19	Other drug induced secondary parkinsonism

G21.2	Secondary parkinsonism due to other external agents
G21.3	Post-encephalitic parkinsonism
G21.4	Vascular parkinsonism
G21.8	Other secondary parkinsonism
G21.9	Secondary parkinsonism, unspecified
G24.1	Genetic torsion dystonia
G24.2	Idiopathic non-familial dystonia
G24.3	Spasmodic torticollis
G24.4	Idiopathic orofacial dystonia
G24.8	Other dystonia
G25.0	Essential tremor
G25.1	Drug-induced tremor
G25.2	Other specified forms of tremors
G40.001	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, with status epilepticus
G40.009	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, without status epilepticus
G40.011	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, with status epilepticus
G40.019	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, without status epilepticus
G40.101	Localization-related (focal) (partial)symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, with status epilepticus
G40.109	Localization-related (focal) (partial)symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, without status epilepticus
G40.111	Localization-related (focal) (partial)symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, with status epilepticus
G40.119	Localization-related (focal) (partial)symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, without status epilepticus
G40.201	Localization-related (focal) (partial)symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, with status epilepticus
G40.209	Localization-related (focal) (partial)symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, without status epilepticus
G40.211	Localization-related (focal) (partial)symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, with status epilepticus
G40.219	Localization-related (focal) (partial)symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, without status epilepticus
G40.301	Generalized idiopathic epilepsy and epileptic syndromes, not intractable, with status epilepticus
G40.309	Generalized idiopathic epilepsy and epileptic syndromes, not intractable, without status epilepticus
G40.311	Generalized idiopathic epilepsy and epileptic syndromes, intractable, with status epilepticus
G40.319	Generalized idiopathic epilepsy and epileptic syndromes, intractable, without status epilepticus
G40.A01	Absence epileptic syndrome, not intractable, without status epilepticus

G40.A09	Absence epileptic syndrome, not intractable, without status epilepticus
G40.A11	Absence epileptic syndrome, intractable, with status epilepticus
G40.A19	Absence epileptic syndrome, intractable, without status epilepticus
G40.B01	Juvenile myoclonic epilepsy, not intractable, with status epilepticus
G40.B09	Juvenile myoclonic epilepsy, not intractable, without status epilepticus
G40.B11	Juvenile myoclonic epilepsy, intractable, with status epilepticus
G40.B19	Juvenile myoclonic epilepsy, intractable, without status epilepticus
G40.401	Other generalized epilepsy and epileptic syndromes, not intractable, with status epilepticus
G40.409	Other generalized epilepsy and epileptic syndromes, not intractable, without status epilepticus
G40.411	Other generalized epilepsy and epileptic syndromes, intractable, with status epilepticus
G40.419	Other generalized epilepsy and epileptic syndromes, intractable, without status epilepticus
G40.501	Epileptic seizures, related to external causes, not intractable, with status epilepticus
G40.509	Epileptic seizures, related to external causes, not intractable, without status epilepticus
G40.801	Other epilepsy, not intractable, with status epilepticus
G40.802	Other epilepsy, not intractable, without status epilepticus
G40.803	Other epilepsy, intractable, with status epilepticus
G40.804	Other epilepsy, intractable, without status epilepticus
G40.811	Lennox-Gastaut syndrome, not intractable, with status epilepticus
G40.812	Lennox-Gastaut syndrome, not intractable, without status epilepticus
G40.813	Lennox-Gastaut syndrome, intractable, with status epilepticus
G40.814	Lennox-Gastaut syndrome, intractable, without status epilepticus
G40.821	Epileptic spasm, not intractable, with status epilepticus
G40.822	Epileptic spasm, not intractable, without status epilepticus
G40.823	Epileptic spasm, intractable, with status epilepticus
G40.824	Epileptic spasm, intractable, without status epilepticus
G40.901	Epilepsy, unspecified, not intractable, with status epilepticus
G40.909	Epilepsy, unspecified, not intractable, without status epilepticus
G40.911	Epilepsy, unspecified, intractable, with status epilepticus
G40.919	Epilepsy, unspecified, intractable, without status epilepticus

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

SUMMARY OF LITERATURE

Summary of Literature

Obsessive-Compulsive Disorder

Hayes Conclusion: Deep Brain Stimulation for OCD – There is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management for deep brain stimulation (DBS) for the treatment of obsessive-compulsive disorder (OCD).

UpToDate: Effective treatments for OCD include cognitive behavioral therapy (CBT) and serotonin reuptake inhibitors. Even when optimal treatment is provided, however, approximately 10 percent of patients remain severely affected with treatment-refractory OCD. Deep brain stimulation (DBS), a treatment in which implanted electrodes send electrical pulses to specific locations in the brain, may be useful for a small proportion of patients with severe, incapacitating OCD that is refractory to other treatments.

An investigational/experimental treatment for obsessive-compulsive disorder (OCD), deep brain stimulation (DBS) is typically used in patients who meet each of the following criteria:

- The presence of primary OCD. While some major co-occurring psychiatric disorders are exclusion criteria, OCD patients treated with DBS may have co-occurring depressive symptoms and/or suicidal ideations.
- OCD should be severe and incapacitating, with a severity score on the Yale-Brown Obsessive Compulsive Scale (Y-BOCS) of at least 28.
- OCD should be treatment-refractory. Treatment refractoriness is generally defined by multiple, unsuccessful trials of an anti-obsessive-compulsive medication at adequate dosing and duration, as well as a poor response to an adequate trial of behavioral therapy

The efficacy of DBS for OCD has not been established, but preliminary trials, either uncontrolled or inadequately controlled, have shown promising results. Of 63 patients with treatment refractory OCD who have received DBS, 34 experienced a reduction of symptoms of 35 percent or more. DBS is an experimental procedure that has been used to treat incapacitating and treatment-refractory OCD. Given the invasive nature of DBS and the lack of efficacy data, we suggest that patients with OCD only be treated with DBS in the context of a clinical trial.

In 2007, the American Psychiatric Association practice guideline for the treatment of patients with obsessive-compulsive disorder states DBS may be recommended on the basis of individual circumstances.

In 2013, the American Psychiatric Association guideline watch practice parameter for the treatment of patients with obsessive-compulsive disorder states DBS and ablative neurosurgical treatment for OCD should be performed only at sites with expertise in both OCD and these treatment approaches.

<u>Depression</u>

Hayes Conclusion: Deep Brain Stimulation for Treatment-Resistant Depression – There is some evidence that deep brain stimulation (DBS) may reduce depressive symptoms of patients with treatment-resistant depression (TRD), and may increase remission rates. However, the evidence should be considered preliminary since all of the studies lacked a control group, and sample sizes were small across studies. In addition, the manufacturer of the DBS equipment supported most of the studies, and individual authors had financial relationships with the manufacturer in several studies. Therefore, based on the evidence, the following Hayes Rating is assigned:

C – For DBS for TRD. This rating reflects early positive outcomes from a small number of studies.

In 2001, the Canadian Psychiatric Association and the Canadian Network for Mood and Anxiety Treatments (CANMAT) partnered to produce evidence-based clinical guidelines for the treatment of depressive disorders. These guidelines were revised by CANMAT in 2008 to 2009 to reflect advances in the field (Kennedy et al., 2009). The revised guidelines stated that there is emerging evidence that DBS is effective for otherwise treatment-resistant depression, but this approach remains an investigational treatment.

The Ontario Health Technology Advisory Committee (OHTAC) is unable to recommend the use of deep brain stimulation for treatment-resistant depression at this time because:

- The device is not licensed in Canada for treatment-resistant depression.
- The evidence suggests a beneficial effect of deep brain stimulation in treatment-resistant depression, however, this conclusion is based on very low quality of evidence.

If Health Canada licenses the product for treatment-resistant depression in Canada, OHTAC will consider reviewing the technology again, if requested to do so. In view of ongoing clinical trial activity in the area, Evidence Development and Standards (EDS), department of the Health Quality Ontario, should update its review and report back to OHTAC in 12 months, if the product has been licensed at that time.

Parkinson's disease

Hayes Conclusion: Vercise Deep Brain Stimulation (DBS) System (Boston Scientific) for Parkinson's disease – There is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management using the Vercise DBS System for the treatment of Parkinson's disease.

The National Institute of Health and Care Excellence (NICE, 2017) considers deep brain stimulation for people with advanced Parkinson's disease whose symptoms are not adequately controlled by best medical therapy.

The Congress of Neurological Surgeons Systematic Review and Evidence-based Guideline on Subthalamic Nucleus and Globus Pallidus Internus Deep Brain Stimulation for the Treatment of Patients with Parkinson's Disease: Executive Summary (2018) states, "Given that bilateral STN DBS [subthalamic nucleus deep brain stimulation] is at least as effective as bilateral GPi DBS [globus pallidus internus deep brain stimulation] in treating motor symptoms of Parkinson's disease (as measured by improvements in UPDRS-III scores [Unified Parkinson's Disease Rating Scale, Part III]), consideration can be given to the selection of either target in patients undergoing surgery to treat motor symptoms."

When the main goal of surgery is reduction of dopaminergic medications in a patient with Parkinson's disease, then bilateral STN DBS should be performed instead of GPi DBS.

Unified Parkinson Disease Rating Scale (UPSRS) is a rating tool used to gauge the course of Parkinson's disease. This scale is the most widely used clinical rating scale for PD. It includes a series of ratings for the typical Parkinson's symptoms and covers all of the movement hindrances associated with the disease. The scale consists of five segments:

1. Mentation, behavior, and mood
2. Activities of daily living
3. Motor sections
4. Modified Hoehn and Yahr scale classified in stages
5. Schwab and England ADL scale classified in percentages

The maximum number of points possible is 199. This score represents the worst (total disability), while a score of zero represents no disability.

Epilepsy

Hayes Conclusion: Deep Brain Stimulation for Refractory Epilepsy – There is sufficient published evidence to evaluate this technology. The study abstracts present conflicting findings regarding the use of DBS of the anterior nucleus of the thalamus to treat refractory epilepsy in adults.

SANTE Trial

In this randomized clinical trial of DBS in the anterior nucleus of the thalamus, 110 adult patients with drug-resistant epilepsy participated. Half of the participants received bilateral DBS of the anterior nuclei of the thalamus, and the remaining half received no stimulation during a 3-month blinded phase followed by unblinded stimulation for all (Salanova et al., 2010). The baseline seizure monthly frequency was 19.5 prior to the trial.

In one month of the blinded phase, the stimulated group had a 29% greater reduction in seizures compared with the control group. Complex partial and 'most severe' seizures were significantly reduced by stimulation. At the 2-year mark, there was a 56% median reduction in seizure activity, 54% of the patients had a seizure reduction of at least 50%, and 14 patients were seizure-free for at least 6 months. The authors reported that benefits of DBS persisted for 2 years with modest complication rates.

Surgical Risks Associated with DBS

Risks associated with the DBS surgical procedure and postoperative period can include: allergic reactions to anesthesia or antibiotics including anaphylaxis, blood clot formation in the extremities, blood clot or air forming in or traveling through the blood stream, brain contusion, brain or cerebrospinal fluid infection or inflammation, CSF leakage; confusion or problems with attention, thinking, or memory (acute or chronic); death; fibrosis around the lead extension; hemiparesis; hemiballism; intracranial hemorrhage; intraparenchymal cyst; pain; seizures; speech or language difficulties; stroke; and injury to structure next to the implant.

POLICY SOURCE(S)

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Policy History

Date	Activity
04/16/2019	Initial policy developed
07/16/2019	QI/UM Committee approval
09/16/2019	Provider effective date