CLINICAL MEDICAL POLICY	
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Products:	Highmark Wholecare℠ Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 16

Policy History

Date	Activity
07/01/2023	Provider Effective date
05/05/2023	PARP Approval
04/19/2023	QI/UM Committee review
04/19/2023	Annual Review: No changes to clinical criteria. Updated 'Summary of Literature' and 'Reference Sources' sections.
07/01/2022	Provider Effective date
05/20/2022	PARP Approval
04/20/2022	QI/UM Committee review
04/20/2022	Annual Review: No changes to clinical criteria. Reformatted Procedure section numbering. Updated FDA approval info and added TAG information to the Governing Bodies section. Updated Summary of Literature and Reference Sources sections.
06/21/2021	Provider effective date
05/10/2021	PARP approval
04/21/2021	QI/UM Committee review
04/21/2021	Annual Review: No changes to clinical criteria. Updated Summary of Literature and References sections. Removed archived Hayes information. Added the phrase "List separately in addition to primary procedure" to CPT codes 61864 and 61868 per the official code description.
07/27/2020	Provider effective date
06/16/2020	PARP approval

04/15/2020	QI/UM Committee review
04/15/2020	Annual Review: Formatting changes; under Procedure section 1 add 'adult' to criteria; updated Summary of Literature and Reference sections; add HCPCS codes as eligible- L8682, L8683, & L8685; add ICD-10 Diagnosis codes G24.02 & G24.09
08/12/2019	Provider effective date
06/07/2019	PARP approval
05/15/2019	QI/UM Committee review
04/16/2019	Initial policy developed

Disclaimer

Highmark Wholecare℠ 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 Wholecare℠ 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.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

Definitions

Prior Authorization Review Panel (PARP) - A panel of representatives from within the PA Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

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. The use of deep brain stimulation (DBS) for the treatment of Essential Tremors (ET) and/or Parkinson Disease (PD) Tremor using the Thalamic Ventralis Intermedius Nucleus (VIM) is considered medically necessary when ALL of the following conditions are met:
   A. The DBS device must be FDA approved and utilized according to the labeled indications; AND
   B. Treatment is either unilateral or bilateral; AND
   C. The patient has received appropriate screening and multidisciplinary evaluation; AND
   D. The diagnosis of ET, which is based on postural or kinetic tremors of hand(s) without other neurologic signs, or the diagnosis of idiopathic PD (presence of at least two (2) cardinal PD features [tremor, rigidity or bradykinesia] that are of a tremor-dominant form); AND
   E. 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
   F. No focal lesion of the basal ganglia at the target site that would negate the result of the thalamic stimulation; AND
   G. Patient's willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.

2. The use of Subthalamic Nucleus (STN) or Globus Interna (GPi) DBS to treat PD is considered medically necessary when ALL of the following conditions are met:
   A. The DBS device must be FDA approved and utilized according to the labeled indications; AND
   B. Treatment is either unilateral or bilateral; AND

C. There is a diagnosis of PD for at least four (4) years based on the presence of at least two (2) cardinal PD features (tremor, rigidity, or bradykinesia); AND
D. The diagnosis of advanced idiopathic PD 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 twelve (12) hours; AND
E. PD is responsive to levodopa on clearly defined 'on' periods; AND
F. Persistent disabling PD symptoms or drug side effects (e.g., dyskinesias, motor fluctuations, or disabling 'off' periods) are present despite optimal medical therapy; AND
G. Patient's willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.

3. Unilateral or bilateral DBS of the internal globus pallidus (GPi) or the STN for patients 7 years of age and older is considered medically necessary for chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis).

4. DBS of the Anterior Nucleus of the Thalamus is considered medically necessary for the treatment of Drug Resistant Focal Epilepsy when ALL of the following conditions are met:
   A. Treatment is requested as a last resort; AND
   B. The patient must be 18 years of age or older with partial onset seizures; AND
   C. The patient has had diagnostic testing that localized no more than two epileptogenic foci; AND
   D. The patient's condition is refractory to three or more antiepileptic medications, as monotherapy or in combination; AND
   E. 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 (3) months; AND
   F. Treatment is bilateral.

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

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

7. When DBS services are considered not medically necessary
   DBS is considered experimental/investigational, and therefore not medically necessary for the treatment of ANY of the following, as there is insufficient evidence of effectiveness:
   - Chronic pain syndrome
   - Chronic cluster headache
   - Headache
   - Degenerative disorders

- Depression
- Head tremors, other tremor disorders (e.g., multiple sclerosis, CVA)
- Infectious disease
- Metabolic disorders
- Myasthenia Gravis
- Obsessive-compulsive disorder (OCD)
- Post trauma/surgical dystonia
- Tourette syndrome
- Vegetative state
- Voice tremors
- Non-idiopathic Parkinson's disease or Parkinson's Plus
- Huntington's disease
- Alzheimer's disease
- Post-traumatic dyskinesia

Any requests for DBS approval that does not meet the guidelines listed above will require a review by a Medical Director on a case-by-case basis.

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

9. Place of Service
   - The proper 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).

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 PD 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.

In 2020, the FDA approved the Medtronic Percept™ PC Deep Brain Stimulation (DBS) system. BrainSense™ technology makes Percept the first DBS neurostimulation system with the ability to chronically capture and record brain signals while delivering therapy to patients with neurologic disorders associated with Parkinson's disease, essential tremor, dystonia, epilepsy or obsessive-compulsive disorder (OCD). Physicians are able to track patient brain signals and correlate these with patient-recorded actions or experiences, such as symptoms, side-effects, or medication intake. This enables more personalized, data-driven neurostimulation treatment.

There is no FDA approved device for the treatment of depression. The use of any deep brain stimulation device outside of listed FDA guidelines will require approval from a Medical Director.

CMS

The Centers for Medicare and Medicaid Services (CMS) has published the following guidance:

- Deep Brain Stimulation for Essential Tremor and Parkinson's Disease (160.24)
- There are no CMS determinations for DBS in the treatment of refractory epilepsy.

The Pennsylvania Department of Human Services Technology Assessment Group (TAG) workgroup meets quarterly to discuss issues revolving around new technologies and technologies or services that were previously considered to be a program exception. During this meeting, decisions are made as to whether or not certain technologies will be covered and how they will be covered. TAG's decisions are as follow:

- Option #1: Approved - Will be added to the Fee Schedule
- Option #2: Approved as Medically Effective - Will require Program Exception
- Option #3: Approved with (or denied due to) Limited/Minimal Evidence of Effectiveness - Will require Program Exception
- Option #4: Denied - Experimental/Investigational

As of March 2019, the TAG workgroup assigned DBS an Option # 3, specifically for CPT/HCPCS codes 61863, 61864, 61886, 61867, 61868, 61885, 61886, L8679, L8686, L8687, & L8688.

Program Exception
DBS requires a program exception. The ordering physician must provide a supporting statement indicating why the requested therapy or device is medically necessary, and the alternative options have been or are likely to be ineffective, adversely affect patient compliance, or cause an adverse reaction.

Summary of Literature

Parkinson's Disease
When patients first start taking their Parkinson's disease (PD) medicines, the benefits usually last throughout the whole day. However, as PD worsens, the patient may notice that the benefit from the medicine doesn't last until the next dose, this is called "wearing off". When the medicine wears off, PD symptoms such as tremor, slowness, and difficulty walking may reappear. When the medication is taken again the symptoms improve again and the good period is called an "ON" period while the bad period is called "OFF". Patients may also develop involuntary movements (twisting and turning) called dyskinesias, which may be troublesome. In some patients, Deep Brain Stimulation (DBS) is used to treat patients with OFF periods and/or dyskinesia that are not controlled with changes in medication. The stimulation of this brain area can improve OFF periods and can reduce dyskinesias. Patients who may not be good candidates for DBS include those with serious memory problems, hallucinations, severe depression and significant imbalance when walking even when ON. Over time, DBS can continue to improve ON periods and dyskinesias. However, DBS doesn't cure PD or stop its progression (International Parkinson and Movement Disorder Society, 2016).

In patients with PD, the physician will refer them to a specialized neurosurgical center for a DBS consultation. In most DBS centers, the evaluation will include:

- An evaluation by a neurologist who specializes in treating PD
- A brain scan (MRI or CT) to be sure there are no brain changes that might prevent surgery
- A consultation with a neurosurgeon who performs the DBS surgery
- A thorough evaluation including memory and thinking (International Parkinson and Movement Disorder Society, 2016)

According to the American Association of Neurological Surgeons, DBS offers a safer alternative to pallidotomy and thalamotomy. DBS of the subthalamic nucleus or globus pallidus may be effective in treating all of the primary motor features of PD and may allow significant reduction of medication.

Lozano and colleagues (2019) published a review on the use of deep brain stimulation. The vast majority of DBS procedures over the past 25 years have been performed for movement disorders, commonly PD. Despite success of this procedure for movement disorders, the device is ineffective for the treatment of

axial symptoms. The authors note that the timing of the DBS procedure is controversial with strong evidence that early surgery may provide more benefit than later.

An article published by the American Academy of Neurology reported the 5-year outcomes from the STN DBS in early-stage PD pilot clinical trial. Participants who completed the 2-year trial participated in this observational follow-up study, which included annual outpatient visits through 5 years. This analysis includes 28 patients who were taking PD medications for 6 months to 4 years at enrollment. Outcomes were analyzed using both proportional odds logistic regression and linear mixed effects models. The results suggest that early DBS reduces the need for and complexity of PD medications while providing long-term motor benefit over standard medical therapy. This study provides Class II evidence that DBS implanted in early-stage PD decreases the risk of disease progression and polypharmacy compared to optimal medical therapy alone (Hacker, et al., 2020).

The Congress of Neurological Surgeons Systematic Review and Evidence-based Guideline on Subthalamic Nucleus and Globus Pallidus Internus DBS for the Treatment of Patients with Parkinson's Disease: Executive Summary (2018) states, "Given that bilateral subthalamic nucleus (STN) DBS 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 (Rughani, Schwalb, et al., 2018).

Epilepsy

DBS for epilepsy a neuromodulation therapy designed to help in the management of refractory seizures. A neurosurgeon places electrodes in the thalamus portion of the brain. The electrodes transmit constant or intermittent stimulation to modulate the excitability of certain circuits of the brain, which in-turn can reduce the frequency of seizures. DBS is used in combination with other treatments in adults with focal epilepsy which does not respond to medication management (Kiriakopoulos, 2020).

DBS was introduced as an option for patients in whom a circumscribed focus amenable for resection could not be identified. There was an expectation that DBS would become a central strategy in epilepsy replacing open respective procedures. These expectations were dampened after the publication of studies that demonstrated efficacy but showed that the majority of patients would not become seizure free While DBS is a promising technology additional exploration is necessary (Lozano et al, 2019).

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. The baseline seizure monthly frequency was 19.5 prior to the trial. (Sante Study Group, 2010).

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 (Salanova et al., 2010).

The anterior thalamic nucleus (ATN) is a common target for deep brain stimulation (DBS) for the treatment of drug-refractory epilepsy. However, no atlas-based optimal DBS (active contacts) target within the ATN has been definitively identified. A retrospective study published in the Journal of Neurosurgery analyzed the relationship between the active contact location and seizure reduction to establish an atlas-based optimal target for ATN DBS. From among 25 patients who had undergone ATN DBS surgery for drug-resistant epilepsy between 2016 and 2018, those who had follow-up evaluations for more than 1 year were eligible for study inclusion. After an initial stimulation period of 6 months, patients were classified as responsive (≥ 50% median decrease in seizure frequency) or nonresponsive (< 50% median decrease in seizure frequency) to treatment. Nineteen patients with drug-resistant epilepsy were followed up for at least a year following bilateral DBS electrode implantation targeting the ATN. Active contacts located more adjacent to the center of gravity of the anterior half of the ATN volume, defined as the anterior center (AC), were associated with greater seizure reduction than those not in this location. Also, the initially nonresponsive patients could end up with much improved seizure reduction by adjusting the active contacts closer to the AC at the final postoperative follow-up. The study found that patients with stimulation targeting the AC may have a favorable seizure reduction, and the authors were able to obtain additional good outcomes after electrode repositioning in the initially nonresponsive patients (Guo, et al., 2020).

Hayes, Inc.

- Deep Brain Stimulation of the Anterior Nucleus of the Thalamus for Treatment of Refractory Epilepsy
    - **C Rating** - For use of deep brain stimulation (DBS) of the anterior nucleus of the thalamus (ANT) in adult patients diagnosed with epilepsy who have uncontrolled, partial-onset seizures (with or without secondary generalization) after ≥ 3 antiepileptic drugs. An overall low-quality body of evidence regarding the use of DBS of the ANT for treatment of refractory epilepsy in patients with partial-onset seizures (with or without secondary generalization) suggests that DBS has the potential to reduce seizure frequency. This result has shown durability in long-term follow-up from a single pivotal RCT as well as multiple observational single-center experiences. Limited evidence suggests that DBS may also reduce seizure severity and improve quality of life (QOL). DBS has the potential for serious AEs as indicated by some studies, but most were transient and did not require termination of DBS treatment. Continued research using well-designed controlled studies is needed to confirm the findings of the pivotal RCT, determine the best DBS treatment parameters, and establish which patients would most benefit from this therapy (Hayes, 2021).

Obsessive-Compulsive Disorder (OCD)

While most patients with OCD eventually respond to treatment with medication and/or behavioral therapy, a small minority do not improve following all conventional treatments. For this small minority, one of the few remaining options is neurosurgery, including DBS. Testing for DBS for OCD began in the late 1990s, with promising early results. While the field of neurosurgery for treatment-resistant OCD has advanced considerably in recent years, further research is needed to both optimize DBS treatment and to better understand how DBS works (which areas of the brain are affected and how). While there is evidence to suggest that DBS could potentially be helpful in reducing OCD symptoms, it has not been concretely proven to do so (Dougherty, Greenberg, 2009).

DBS treatment for OCD, has been considered as a last treatment resort by most of learned societies in psychiatry. In 2014, the World Society for Stereotactic and Neurosurgical Surgery (WFSNN) mentioned that to make a significant conclusion about DBS effectiveness for a target in psychiatric disorders, two studies managed by two different teams are necessary. At present, the literature does not conform to these criteria and the most recent meta-analysis failed to show the superiority of a stimulation target to treat OCD. Also, International Guidelines Organizations accord to support the use of DBS as a last resort clinical treatment for OCD only in a research framework in which data are being systematically collected (Tastevin, et al. 2019).

Hayes, Inc.

- Deep Brain Stimulation for the Treatment of Refractory Obsessive-Compulsive Disorder
    - **D2 Rating** - For the use of DBS as an add-on therapy for OCD in adult patients with inadequate responses to ≥ 3 prior treatments and no contraindications to DBS. An overall very-low-quality body of evidence suggests that the effectiveness of DBS for treatment of highly refractory OCD remains uncertain despite several double-blind, crossover trials. Findings of benefit in the primary outcome (Y-BOCS reduction) occurred in nearly all studies and subgroup analyses where a statistical analysis is made; a majority of studies reported that > 50% of patients achieved clinical response by end of active stimulation phase. However, due to the largely unpowered nature of these trials, a total of only 143 patients included across these studies, heterogeneity in stimulation parameters and regions stimulated, and varying levels of concurrent medical and behavioral therapy management, it is challenging to determine who will most benefit from DBS. The very small sample sizes and paucity of long-term follow-up data are also a concern when considering the safety of DBS, as uncommon safety events may not be detectable in such a small evidence base over a shorter-term period. Additional studies that are adequately powered with consistent reporting of non-primary outcome measures and long-term follow-up would help to inform whether DBS offers any sustained benefit to individuals with refractory OCD. Specifically, studies comparing DBS with clinical alternatives in a non-crossover design would help to inform whether DBS is indeed a viable treatment option (Hayes, 2021).

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 (Rosenberg, 2020).

The American Psychiatric Association (APA) 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. The guideline recommends that other somatic therapies, including DBS, “should be considered only after first- and second-line treatments and well-supported augmentation strategies have been exhausted” (APA, 2013).

Depression

DBS is a new therapeutic approach for treatment-resistant depression (TRD). There is a preliminary evidence of the efficacy and safety of DBS for TRD in several parts of the brain. Optimal stimulation targets, however, have not yet been determined. DBS is now being applied, though off-label only, in the treatment of major depression. An optimal approach has yet to be established, as the neuropathophysiology of depression remains weakly defined, and the mechanism of DBS seems to be dependent on the stimulation site. The best targets, parameters of stimulation, and stimulation protocols have not yet been determined. Because of this, DBS in the treatment of depression should be still considered as an experimental therapy (Drobisz, Damborská, 2019).

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 2009 to reflect advances in the field. 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 Kennedy et al., 2009).

Surgical Risks Associated with DBS
In patients who are properly selected, DBS is safe and effective. Risks and potential side effects do exist, but they are generally mild and reversible. Risks may include:

- 1% risk of brain hemorrhage, including stroke
- Infection
- Device malfunction
- Lack of benefit for certain symptoms
- Headache
- Worsening mental or emotional status

During stimulation, side effects may include:

- Temporary tingling in the face or limbs
- A feeling of pulling in muscles
- Speech or vision problems
- Loss of balance (Pilitsis, Khazen, Patel)

Coding Requirements

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

CPT Code	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 (List separately in addition to primary procedure)

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 (List separately in addition to primary procedure)
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 2 or more electrode arrays
HCPCS Code	**Description**
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
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

Diagnosis Codes

ICD-10 Code	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
G24.02	Drug induced acute dystonia
G24.09	Other drug induced 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, with 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 Wholecare℠ contract.

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