Deep Brain Stimulation

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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 medical surgical benefits of the company's Medicaid products for medically necessary 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

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children (DHCP) and Diamond State Health Plan Plus members.

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 function is 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. A prior authorization is required.

2. Medical necessity guidelines.

    - Essential Tremors (ET) and/or Parkinson Disease (PD) Tremor Using the Thalamic Ventral Intermediate Nucleus (VIM) DBS.
        - The DBS device must be FDA approved and utilized according to the labeled indications; and
        - Treatment may be unilateral or bilateral; and
        - The patient has received appropriate screening and multidisciplinary evaluation; and
        - The diagnosis of ET which is based on postural or kinetic tremors of hand(s) without other neurologic signs; or
        - Diagnosis of idiopathic PD (presence of at least 2 cardinal PD features [tremor, rigidity or bradykinesia] that are of a tremor-dominant form); and
        - 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
        - No focal lesion of the basal ganglia at the target site that would negate the result of the thalamic stimulation; and
        - Patient willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.
    - Parkinson Disease Treatment with Subthalamic Nucleus (STN) or Globus Interna (GPi) DBS.

- The DBS device must be FDA approved and utilized according to the labeled indications; and
- Treatment may be unilateral or bilateral; and
- Diagnosis of PD for at least 4 years based on the presence of at least 2 cardinal PD features (tremor, rigidity, or bradykinesia); and
- 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
- PD responsive to levodopa on clearly defined 'on' periods; and
- Persistent disabling PD symptoms or drug side effects (e.g., dyskinesias, motor fluctuations, or disabling 'off' periods) are present despite optimal medical therapy; and
- 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).

- Drug Resistant Focal Epilepsy with Anterior Nucleus of the Thalamus DBS
  - Treatment is requested as a last resort; and
  - The patient must be 18 years of age or older; and
  - The patient has had diagnostic testing that localized no more than two epileptogenic foci; and
  - The patient has partial onset seizures; and
  - The patient's condition is refractory to three or more antiepileptic medications, as monotherapy or in combination; and
  - 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
  - Treatment is bilateral.

3. Contraindications

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

4. Precautions

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

5. 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:

- 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

6. 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.

7. Place of service: inpatient

CODING REQUIREMENTS

CPT Codes	Description
61850	Twist drill or burr hole(s) for implantation or neurostimulator electrodes; cortical.
61860	Craniectomy or craniotomy for implantation of neurostimulator electrodes, cerebral; cortical.
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 recording; 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 recording; each additional array (list separately in addition to primary procedure).
61880	Revision or removal of intracranial neurostimulator electrodes.
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays.
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array.
61888	Revision or removal of cranial neurostimulator pulse generator or receiver
95836	Electrocorticogram from an implanted brain neurostimulator pulse generator/transmitter, including recording, with interpretation and written report, up to 30 days.
95961	Functional cortical and subcortical mapping by stimulation and/or recording of electrodes on brain surface, or of depth electrodes, to provoke seizures or identify vital brain structures, initial hour of physician attendance.
95962	Functional cortical and subcortical mapping by stimulation and/or recording of electrodes on brain surface, or of depth electrodes, to provoke seizures or identify vital brain structures, each additional hour of physician attendance (list separately in addition to code for primary procedure).
95970	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode select ability, output modulation, cycling, impedance and patient compliance measurement(s), simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) Neurostimulator pulse generator/transmitter, without reprogramming.
95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group(s), interleaving, amplitude, pulse width, frequency [hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional.
95977	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group(s), interleaving, amplitude, pulse width, frequency [hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional.
95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group(s), interleaving, amplitude, pulse width, frequency [hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face with physician or other qualified health care professional.
95984	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group(s), interleaving, amplitude, pulse width, frequency [hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face with physician or other qualified health care professional.

HCPCS Codes	Description
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only.
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver.
L8684	Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement.
L8689	neurostimulator and accessories.
L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only.

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

DIAGNOSIS CODES

Codes						
G20	G25.1	G21.11	G25.2	G21.19	G40.001	G21.2
G40.009	G21.3	G40.011	G21.4	G40.019	G21.8	G40.101
G21.9	G40.109	G24.1	G40.111	G24.2	G40.119	G24.3
G40.201	G24.4	G40.209	G24.8	G40.211	G25.0	G40.219

REIMBURSEMENT

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

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).

Up to date: 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.

Depression
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.

Reference

American Association of Neurological Surgeons. Deep brain stimulation. 2007. Accessed on April 23, 2019.

Canadian Psychiatric Association and the Canadian Network for Mood and Anxiety Disorders (CANMAT).

Centers for Medicaid and Medicare Services (CMS), National Coverage Determination for Deep Brain Stimulation for Essential Tremor and Parkinson's disease (NCD 160.4). Effective April 1, 2003. Accessed on April 16, 2019.

Department of Health and Human Services. Technology Assessment Group Coverage Decisions. Managed Care Operations Memorandum: General Operations: MCOPS Memo #03/2019-005. Accessed on April 19, 2019.

Evidence based guidelines for the treatment of depressive disorders. Journal of Affective Disorders.117 (Suppl 1): S44-53. September 2009. Accessed on May 3, 2019.

Hayes Inc. Deep brain stimulation for obsessive compulsive disorder. Lansdale, PA: Hayes, Inc.; May 2018. Accessed on April 17, 2019.

Hayes, Inc. Deep brain stimulation of the anterior nucleus of the thalamus for the treatment of refractory epilepsy. Lansdale, PA: Hayes, Inc.; April 11, 2019. Accessed on April 23, 2019.

Hayes, Inc. Hayes Clinical Research Response. Infinity DBS System for Movement disorders. Lansdale, PA; Hayes, Inc.; June 15, 2017. Archived August 6, 2018. Accessed on April 17, 2019.

Hayes, Inc. Vercise deep brain stimulation (DBS) system (Boston Scientific) for Parkinson's disease. Lansdale, PA: Hayes, Inc.; January 22, 2019.

National Institute for Health and Care Excellence (NICE): NICE guideline [NG71]. Parkinson's disease in adults. Published date: July 2017. Accessed on April 23, 2019.

Salanova FR, Witt T, Worth R, Gross R, Oommen K, Osorio I, Nazzaro J, Labar D, Kaplitt M, Sperling M, Sandok E, Neal J, Handforth A, Stern J, DeSalles A, Chung S, Shetter A, Bergen D, Bakay R, Henderson J, French J, Baltuch G, Rosenfeld W, Youkilis A, Marks W, Garcia P, Barbaro N, Fountain N, Bazil C, Goodman R, McKhann G, Babu Krishnamurthy K, Papavassiliou S, Epstein C, Pollard J, Tonder L, Grebin J, Coffey R, Graves N, SANTE Study Group. Electrical Stimulation of the anterior nucleus of thalamus for treatment of refractory epilepsy. Epilepsia. 2010;51(5):899. Epub 2010 March 17. Accessed April 23, 2019.

Sirven JI. UpToDate. Evaluation and management of drug-resistant epilepsy. Last updated Dec 20, 2018. Accessed on April 23, 2019.

The American Psychiatric Association (APA). Guideline Watch; March 2013: Practice guideline for the treatment of patients with obsessive-compulsive disorder. Accessed April 17, 2019.

POLICY UPDATE HISTORY

08/19/2021	Approved in Medical Policy Committee
01/31/2022	Annual review of policy.
02/23/2022	Approved in Medical Policy Committee