Deep Brain Stimulation

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Approved By:	Highmark Health Options – Market Leadership
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Products:	Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 8

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 Program (DHCP) and Diamond State Health Plan Plus LTSS (DSHP Plus LTSS) 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 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

A prior authorization is required.

Unilateral or bilateral DBS of the thalamic ventralis intermedius nucleus (VIM) may be considered medically necessary for the treatment of intractable tremors due to essential tremor or PD when ALL of the following criteria are met:

- Diagnosis of essential tremor or idiopathic PD (with the presence of at least two (2) cardinal PD features - tremor, rigidity, bradykinesia) that is not responding satisfactorily to drug therapy; and
- No diagnosed dementia, severe depression, cerebral atrophy, or Hoehn and Yahr stage V PD; and
- No focal lesion of the basal ganglia (e.g., a space occupying lesion or lacunae) at the target site that would negate the result of thalamic stimulation; and
- Sufficient residual motor function in the upper extremity so that it is reasonable to expect an improvement following the surgery; and
- Willingness and ability of the individual to cooperate during a conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.

Unilateral or bilateral DBS of the subthalamic nucleus (STN) or globus pallidus interna (GPi) for the treatment of PD may be considered medically necessary when ALL of the following criteria are met:

- PD of at least four (4) years duration; and
- PD (with the presence of at least two (2) cardinal PD features - tremor, rigidity, bradykinesia) that is not responding satisfactorily to drug therapy; and
- Presence of disabling PD symptoms or medication side effects (e.g., dyskinesia's, motor fluctuations, or disabling "off" periods) despite optimal medical therapy; and

- No diagnosed dementia, severe depression, cerebral atrophy, or Hoehn and Yahr stage V PD; and
- PD is levodopa responsive with clearly defined "on" periods; and
- Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.

DBS may be considered medically necessary when it is used as a treatment for chronic intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis) in individuals seven (7) years of age or older.

Intensive electronic analysis and programming of a deep brain stimulator may be necessary immediately following implantation to achieve optimal stimulus parameters. Recognizing these needs, six (6) such programming visits will be covered within 60 days of the surgical implantation of the deep brain stimulator, and once every 30 days thereafter, as necessary.

DBS is considered experimental/investigational and therefore, noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature when used in ANY ONE of the following situations:

- For other movement disorders, including but not limited to multiple sclerosis, post-traumatic dyskinesia, and tardive dyskinesia; or
- For treatment of tremor from other causes such as trauma, degenerative disorders, metabolic disorders, or infectious diseases; or
- For other indications, including cluster headaches, refractory depression, and Tourette's syndrome.

Bilateral stimulation of the anterior nucleus of the thalamus may be considered medically necessary when ALL of the following criteria have been met:

- Age 18 years and older; and
- Individuals with partial onset seizures with or without secondary generalization to tonic-clonic activity; and
- Individuals with no response to three (3) or more antiepileptic medications; and
- The individual has an average of six (6) or more seizures per month, over the three (3) most recent months prior to DBS implantation (with no more than 30 days in between seizures).

Note: DBS has not been evaluated in individuals with less frequent seizures.

Bilateral stimulation of the anterior nucleus of the thalamus not meeting the criteria as indicated in this policy is considered not medically necessary.

UNITED STATES FEDERAL FOOD AND DRUG ADMINISTRATION (U.S. FDA)

Humanitarian Device Exemption (HDE)

DBS is U.S. FDA HDE approved for the indication of bilateral stimulation of the anterior limb of the internal capsule, aic, in obsessive compulsive disorder (OCD) when ALL of the following criteria have been met:

- Age 18 or older; and
- As an adjunct to medication(s); and
- As an alternative to anterior capsulotomy for the treatment of chronic, severe, treatment-resistant OCD; and

- For individuals that have failed at least three (3) or more selective serotonin reuptake inhibitors (SSRIs); and
- Approved by the institutional review board (IRB) or an appropriate local committee; and
    - Note: Appropriate local committee is defined by the U.S. FDA as a standing committee that has expertise and experience in reviewing and making treatment decisions for clinical care, particularly in applying innovative medical device technologies.
- Performed in a facility with IRB oversight.
    - Note: Documentation of IRB approval may be required to ensure compliance with HDE indications and applications.

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.

PLACE OF SERVICE: INPATIENT/OUTPATIENT

Experimental/Investigational (E/I) services are not covered regardless of place of service.

Deep Brain Stimulation is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a co-morbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

CODING REQUIREMENTS

CPT code	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.
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.

DIAGNOSIS CODES

COVERED DIAGNOSIS CODES FOR PROCEDURE CODES: 61863, 61864, 61867, 61868, 61885, AND 61886

Codes						
G20	G21.0	G21.11	G21.19	G21.2	G21.3	G21.4
G21.8	G21.9	G24.09	G24.1	G24.2	G24.3	G24.4
G24.8	G24.9	G25.0	G25.1	G25.2	G25.89	G40.001
G40.009	G40.011	G40.019	G40.101	G40.109	G40.111	G40.119
G40.201	G40.209	G40.211	G40.219	Z45.42		

REIMBURSEMENT

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

Reference

Troster AI, Meador KJ, Irwin CP, Fisher RS, Group SS. Memory and mood outcomes after anterior thalamic stimulation for refractory partial epilepsy. Seizure. 2017; 45:133-141.

FDA. Premarket Approval (PMA) Database. Medtronic DBS System for Epilepsy.

FDA. Premarket Approval (PMA) Database. Metronic Activa Termor Control System.

FDA. Premarket Approval (PMA) Database. Metronic Activa Parkinson's Control System.

FDA. Humanitarian Device Exemptions (HDE) Database. Medtronic Activa Deep Brain Stimulation (DBS) System.

Hayes Inc. Health Technology Assessment. Deep Brain Stimulation of the Anterior Nucleus of the Thalamus for Treatment of Refractory Epilepsy. Lansdale, PA: Hayes, Inc.; 11/14/2019.

Hayes, Inc. Evidence Analysis Research Brief. Deep Brain Stimulation for Obsessive Compulsive Disorder. Lansdale, PA: Hayes, Inc.; 08/19/2020.

Bhidayasiri R, Jitkritsadakul O, Friedman JH, et al. Updating the recommendations for treatment of tardive syndromes: A systematic review of new evidence and practical treatment algorithm. J Neurol Sci. 2018; 389:67-75.

Pringsheim T, Okun MS, Muller-Vahl K, et al. Practice guideline recommendations summary: Treatment of tics in people with Tourette syndrome and chronic tic disorders. Neurology. 2019; 92(19): 896-906.

Li HX, He L, Zhang CC, et al. Deep brain stimulation in post-traumatic dystonia: A case series study. CNS Neurosci Ther. 2019;25(11):1262-9.

Martinez-Ramirez D, Jimenez-Shahed J, Leckman JF, et al. Efficacy and safety of deep brain stimulation in Tourette syndrome: The international Tourette syndrome deep brain stimulation public database and registry. JAMA Neurol. 2018;75(3):353-9.

Rapinesi C, Kotzalidis GD, Ferracuti S, et al. Brain stimulation in obsessive-compulsive disorder (OCD): A systematic review. Curr Neuropharmacol. 2019;17(8):787-807.

Farrand S, Evans AH, Mangelsdorf S. Deep brain stimulation for severe treatment-resistant obsessive-compulsive disorder: An open-label case series. Aust N Z J Psychiatry. 2018;52(7):699-708.
Guzick A, Hunt PJ, Bijanki KR, et al. Improving long term patient outcomes from deep brain stimulation for treatment-refractory obsessive-compulsive disorder. Expert Rev Neurother. 2020;20(1):95-107.

Artusi CA, Farooqi A, Romagnolo A, et al. Deep brain stimulation in uncommon tremor disorders: Indications, targets, and programming. J Neurol. 2018;265(11):2473-93.

Kim SH, Lim SC, Kim J, et al. Long-term follow-up of anterior thalamic deep brain stimulation in epilepsy: An 11-year, single center experience. Seizure. 2017; 52:154-161.

Tröster AI, Meador KJ, Irwin CP, Fisher RS; SANTE Study Group. Memory and mood outcomes after anterior thalamic stimulation for refractory partial epilepsy. Seizure. 2017; 45:133-141.

Bouwens van der Vlis TAM, Schijns OEMG, Schaper FLWVJ, et al. Deep brain stimulation of the anterior nucleus of the thalamus for drug-resistant epilepsy. Neurosurg Rev. 2019;42(2):287-296.

Rodrigues FB, Duarte GS, Prescott D, Ferreira J. Deep brain stimulation for dystonia. Cochrane Database Syst Rev. 2019;1(1):CD012405.

Moro E, LeReun C, Krauss JK, Albanese A. Efficacy of pallidal stimulation in isolated dystonia: A systematic review and meta-analysis. Eur J Neurol. 2017;24(4):552-560.

Wong JK, Cauraugh JH, Ho KWD, Broderick M. STN vs. GPi deep brain stimulation for tremor suppression in Parkinson disease: A systematic review and meta-analysis. Parkinsonism Relat Disord. 2019; 58:56-62.

Wu H, Hariz M, Visser-Vandewalle V, Zrinzo L. Deep brain stimulation for refractory obsessivecompulsive disorder (OCD): Emerging or established therapy? Mol Psychiatry. 2021;26(1):60-65.

Rapinesi C, Kotzalidis GD, Ferracuti S, Sani G. Brain stimulation in obsessive-compulsive disorder (OCD): A systematic review. Curr Neuropharmacol. 2019;17(8):787-807.

Ranjan M, Ranjan N, Deogaonkar M, Rezai A. Deep brain stimulation for refractory depression, obsessive-compulsive disorder and addiction. Neurol India. 2020;68(Supplement):S282-S287.

Vázquez-Bourgon J, Martino J, Sierra Peña M, Infante Ceberio J. Deep brain stimulation and treatment-resistant obsessive-compulsive disorder: A systematic review. Rev Psiquiatr Salud Ment (Engl Ed). 2019;12(1):37-51.

Kohl S, Baldermann JC. Progress and challenges in deep brain stimulation for obsessivecompulsive disorder. Pharmacol Ther. 2018; 186:168-175.

Moro E, LeReun C, Krauss JK, et al. Efficacy of pallidal stimulation in isolated dystonia: A systematic review and meta-analysis. Eur J Neurol. 2017;24(4):552-560.

Malek N. Deep Brain Stimulation in Parkinson's Disease. Neurol India. 2019;67(4):968-978. 29. Wong JK, Hess CW, Almeida L, et al. Deep brain stimulation in essential tremor: Targets, technology, and a comprehensive review of clinical outcomes. Expert Rev Neurother. 2020;20(4):319-331.

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
03/22/2023	Annual review; approved in Medical Policy Committee
03/28/2023	Approved in QI/UM