MEDICAL COVERAGE POLICY	
SERVICE:	**Deep Brain Stimulation**
Policy Number:	**025**
Effective Date:	**07/01/2020**
Last Review:	**05/28/2020**
Next Review Date:	**05/28/2021**

Important note:
Unless otherwise indicated, this policy will apply to all lines of business.
Even though this policy may indicate that a particular service or supply may be considered medically necessary and thus covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage (EOC) or Summary Plan Description (SPD) to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare-linked plan members, this policy will apply unless there are Medicare policies that provide differing coverage rules, in which case Medicare coverage rules supersede guidelines in this policy. Medicare-linked plan policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website. Similarly, for Medicaid-linked plans, the Texas Medicaid Provider Procedures Manual (TMPPM) supersedes coverage guidelines in this policy where applicable.

SERVICE: Deep brain stimulation

PRIOR AUTHORIZATION: Required.

POLICY: Please review the plan's EOC (Evidence of Coverage) or Summary Plan Description (SPD) for coverage details.

For Medicare plans, please refer to appropriate Medicare NCD (National Coverage Determination) or LCD (Local Coverage Determination).

For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid TMPPM.

Commercial lines of business will use the criteria set forth in InterQual®. When the InterQual® criteria-set only includes Medicare sources, i.e., National or Local Coverage Determinations, those sources will be used to review requests for commercial lines of business.

Similarly, for **Medicaid** lines of business, if the service is a benefit and criteria are not set forth in the TMPPM, Medicaid lines will use InterQual as indicated for commercial lines above.

OVERVIEW: Deep brain stimulation (DBS) consists of electrical stimulation of specific sites in the brain with implanted electrodes to reduce the symptoms of movement disorders such as Parkinson's disease and Essential Tremor. Targeted areas include the ventral intermediate nucleus of the thalamus, the internal globus pallidus and the subthalamic nucleus. Each of these brain regions has two halves which control movement on opposite sides of the body. Unilateral DBS is used in patients when the symptoms are more severe on one side. Bilateral DBS is used for treatment of bilateral symptoms.

At the present time, there are two devices that have been approved by the FDA for deep brain stimulation. The Medtronic Activa® originally received FDA premarket approval (PMA) on July 31, 1997 for unilateral implantation in the subthalamic thalamus for the suppression of tremor in the upper extremity in patients who are diagnosed with Essential Tremor or Parkinsonian tremor not adequately controlled with medications and where the tremor constitutes a significant functional disability which interferes with one or more activities of daily living (ADL's). The device received FDA approval for the bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus

(STN) as an adjunctive therapy in reducing some of the symptoms of advanced, levodopa-responsive Parkinson's disease that are not adequately controlled with medication as January 14, 2002. The original approval and links to all of the FDA-approved supplements to the Medtronic device are available at the FDA website: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/PMA.cfm?ID=7024.

Under the Humanitarian use Device exemption the FDA approved the Medtronic Activa® for unilateral or bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) to aid in the management of chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis) in patients seven years of age or above. (April 15, 2003)

The FDA approved the Medtronic Reclaim TM Deep Brain Stimulation device for Obsessive Compulsive Disorder (OCD) on February 19, 2009. The peer-reviewed published literature includes several case series studies and one small 10-month randomized sham- controlled crossover study supporting use of the device in OCD. Mallet et al. conclude (2008) that "stimulation of the subthalamic nucleus may lessen the severity of obsessive–compulsive symptoms and improve global functioning in patients with refractory, severe OCD." Serious adverse events occurred in 11 of the 17 patients in whom stimulators were implanted. The occurrence of severe adverse events, the small number of patients, and the short duration of the study highlight the risks of stimulation of the subthalamic nucleus and the need for larger studies with longer follow-up.

MANDATES: none

CODES:

Coding for deep brain stimulation consists of a series of CPT codes describing the various steps of the procedure, i.e., implantation of the electrodes, implantation of the pulse generator, intra-operative monitoring and programming of the electrodes, and postoperative neuro-programming. Patients may undergo several sessions of electronic analysis with or without programming to find the optimal programming parameters.

For bilateral stimulation via implantation of two cranial neurostimulator pulse generators, each connected to a single lead, add modifier -50 to either 81885 or 61886. For bilateral stimulation via implantation of one cranial neurostimulator pulse generator, connected to two leads, use 61886. The device codes (L8680, L8681, L8686 and L8688) are used by the entity that supplies the device to the plan member. For implanted devices, this is typically the facility. Surgically implanted devices are not subject to the plan member's durable medical equipment benefit limit.

Important note:
CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT codes:	61863 Twist drill, burr hole, craniotomy or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, 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 (eg, 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 eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording, each additional array (List separately in addition to primary procedure), +61868 Twist drill burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus palidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; each additional array 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 attendance by a physician or other qualified health care professional +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 attendance by a physician or other qualified health care professional (List separately in addition to code for primary procedure), 95970 Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode select ability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (ie, cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming, 95974 Electronic analysis of implanted neurostimulator pulse generator system; complex cranial nerve neurostimulator pulse generator/transmitter with intraoperative/subsequent programming with/without nerve interface testing, first hour +95975 Electronic analysis of implanted neurostimulator pulse generator system; complex cranial nerve neurostimulator pulse generator/transmitter with intraoperative/subsequent programming, each additional 30 minutes after first hour 95978 Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, battery status, electrode select ability and polarity, impedance and patient compliance measurements), complex deep brain neurostimulator pulse generator /transmitter, with initial or subsequent programming; first hour, +95979 Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, battery status, electrode select ability and polarity, impedance and patient compliance measurements), complex deep brain neurostimulator pulse generator/transmitter, with initial or subsequent programming; each additional 30 minutes after first hour (List separately in addition to code for primary procedure).

HCPCS codes	L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688, L8689 C1767 Generator, neurostimulator (implantable), non-rechargeable C1778 Neurostimulator lead (implantable) C1787 Patient programmer neurostimulator C1816 Receiver/transmitter neurostimulator (implantable) C1820 Generator, neurostimulator (implantable), non high-frequency with rechargeable battery and charging system C1883 Adaptor/extension, pacing lead or neurostimulator lead (implantable) C1897 Neurostimulator lead test kit (implantable) E0745 Neuromuscular stimulator, electronic shock unit L8679 Implantable neurostimulator, pulse generator, any type 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 Radiofrequecy 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, L8688mplantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension, L8689 External recharging system for battery (internal) for use with implantable neurostimulator, replacement only. L8695 External recharging system for battery external) for use with implantable neurostimulator, replacement only.
ICD10 codes:	G20: Parkinson's disease G24.1 - G24.9: G24.1: Genetic torsion dystonia G24.2: Idiopathic nonfamilial dystonia G24.3: Spasmodic torticollis G24.8: Other dystonia G24.9: Dystonia, unspecified G25.0: Essential tremor G25.2: Other specified forms of tremor M43.6: Torticollis

CMS: CMS issued a National Coverage Determination (NCD 160.24) on February 12, 2003 regarding Medicare coverage of DBS for the treatment of Essential Tremor and Parkinson's Disease. The NCD states that, effective April 1, 2003, Medicare will cover unilateral or bilateral thalamic Vim DBS for the treatment of Essential Tremor and/or Parkinsonian tremor and unilateral or bilateral STN or GPi DBS for the treatment of Parkinson's Disease only under the following conditions:

- DBS devices must be FDA-approved devices for DBS or devices used in accordance with FDA-approved protocols governing Category B Investigational Device Exemption (IDE) DBS clinical trials.

For thalamic Vim DBS to be considered reasonable and necessary, patients must meet all of the following criteria:

- Diagnosis of Essential Tremor based on postural or kinetic tremors of the hand(s) without other neurologic signs, or diagnosis of idiopathic Parkinson's Disease P, defined as the presence of at least two cardinal Parkinson's Disease features (tremor, rigidity, or bradykinesia), which is of a tremor-dominant form.
- 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.
- Willingness and ability to cooperate during a conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications, and stimulator settings.

For STN or GPi DBS to be considered reasonable and necessary, patients must meet all of the following criteria:

- Diagnosis of Parkinson's Disease based on the presence of at least two cardinal Parkinson's Disease features (tremor, rigidity, or bradykinesia).
- Advanced idiopathic Parkinson's Disease as determined by the use of Hoehn and Yahr stage or Unified Parkinson's Disease Rating Scale (UPDRS) part III motor subscale.
- Levodopa responsive with clearly defined "on" periods.
- Persistent disabling Parkinson's symptoms or drug side effects (e.g., dyskinesias, motor fluctuations, or disabling "off" periods) despite optimal medical therapy.
- Willingness and ability to cooperate during a conscious operative procedure, as well as during postsurgical evaluations, adjustments of medications and stimulator settings.

CMS does NOT consider DBS as reasonable and necessary and will not cover DBS for Essential Tremor or Parkinson's Disease patients with any of the following:

- Non-idiopathic Parkinson's disease or "Parkinson's Plus" syndromes.
- Cognitive impairment, dementia, or depression that would be worsened by or would interfere with the patient's ability to benefit from DBS.
- Current psychosis, alcohol abuse, or other drug abuse.
- Structural lesions such as basal ganglionic stroke, tumor, or vascular malformation as etiology of the movement disorder.
- Previous movement disorder surgery within the affected basal ganglion.
- Significant medical, surgical, neurologic, or orthopedic comorbidities contraindicating DBS surgery or stimulation.

POLICY HISTORY:

Status	Date	Action
New	8/1/2010	New policy
Reviewed	10/5/2010	Reviewed.
Reviewed	10/17/2011	Reviewed.
Reviewed	11/15/2012	Reviewed.
Reviewed	11/14/2013	ICD10 codes added
Reviewed	09/25/2014	Exclusions clarified
Reviewed	09/24/2015	No changes
Reviewed	09/08/2016	Removed duplicate paragraph. No content change
Reviewed	08/22/2017	Updated codes and references
Reviewed	0612/2018	No changes

Reviewed	07/25/2019	Updated code list and criteria
Updated	05/28/2020	Transition to IQ and aligned for FirstCare and SWHP

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

1. Centers for Medicare & Medicaid Services (CMS) National Coverage Determination for Deep Brain Stimulation for Essential Tremor and Parkinson's disease (160.24)
2. U. S. Food and Drug Administration (FDA) Medtronic Activa® Parkinson's Control Therapy – P960009/S007, Summary of Safety and Effectiveness. http://www.fda.gov/cdrh/pdf/p960009S7.html.
3. U. S. Food and Drug Administration. Medtronic Activa® Parkinson's Control Therapy – P960009, http://www.fda.gov/cdrh/pdf/p960009.pdf
4. Vadailhet, et al. Deep-Brain Stimulation for Generalized Dystonia. New England Journal of Medicine 2005 Feb 3; 352(5):459-67.
5. Medtronic. Medtronic Activa® Therapy: Important Safety Information.
6. Mallet Luc, Polosan M, Jaafari N, et al. Subthalamic Nucleus Stimulation in Severe Obsessive-Compulsive Disorder. N Engl J Med 2008;359(20):21 21-34.
7. U.S. Food and Drug Administration. ReclaimTM Deep Brain Stimulation for Obsessive Compulsive Disorder (OCD) Therapy – H050003. Issued February 19, 2009.
8. Kiss, ZHT, Doig-Beyaert K, Eliasziw M, et al. The Canadian Multicentre Study of Deep Brain Stimulation for Cervical Dystonia. Brain 2007;130:2879-86.
9. Policies Template.docHayes Update Search. Deep Brain Stimulation for Treatment of Dystonia. November 18, 2008. © 2008 Winifred S. Hayes, Inc.
10. Sclerosis, November 6, 2006.
11. MC Rodriguez-Oroz, J.A. Obeso , et al. Bilateral deep brain stimulation in Parkinson's disease: a multicenter study with 4 years follow-up. Brain, Volume 128, Issue 10, 1 October 2005, Pages 2240-2249. Available at: https://academic.oup.com/brain/article/128/10/2240/274634#3352833
12. Lyons, Mark K. "Deep Brain Stimulation: Current and Future Clinical Applications." Mayo Clinic Proceedings 86.7 (2011): 662–672. PMC. Web. 21 Aug. 2017. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3127561/
13. Hickey Patrick, Stacy, Mark, "Deep Brain Stimulation: A Paradigm Shifting Approach to Treat Parkinson's Disease." Front. Neurosci., 28 April 2016. Available at: http://journal.frontiersin.org/article/10.3389/fnins.2016.00173/full
14. American Association of Neurological Surgeons (AANS). "A pilot study of deep brain stimulation in treatment-resistant schizophrenia." ScienceDaily. ScienceDaily, 25 April 2017. <www.sciencedaily.com/releases/2017/04/170425153818.htm>.