MEDICAL COVERAGE POLICY	
SERVICE:	**Deep Brain Stimulation**
Policy Number:	**025**
Effective Date:	**05/01/2024**
Last Review:	**03/11/2024**
Next Review:	**03/11/2025**

Important note: *Unless otherwise indicated, medical policies will apply to all lines of business. Medical necessity as defined by this policy does not ensure the benefit is covered. This medical policy does not replace existing federal or state rules and regulations for the applicable service or supply. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan documents. See the member plan specific benefit plan document for a complete description of plan benefits, exclusions, limitations, and conditions of coverage. In the event of a discrepancy, the plan document always supersedes the information in this policy.*

SERVICE: Deep brain stimulation

PRIOR AUTHORIZATION: Required.

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

Note: Unless otherwise indicated (see below), this policy will apply to all lines of business.

For Medicare plans, please refer to appropriate Medicare NCD (National Coverage Determination) NCD 160.24 Deep Brain Stimulation for Essential Tremor and Parkinson's Disease or LCD (Local Coverage Determination) . Medicare NCD or LCD specific InterQual criteria may be used when available. If there are no applicable NCD or LCD criteria, use the criteria set forth below.

For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid Provider Procedures Manual | TMHP (TMPPM). If there are no applicable criteria to guide medical necessity decision making in the TMPPM, use the criteria set forth below for Commercial plans.

For Commercial plans, 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.

BACKGROUND: 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.

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: *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 (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, 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 (e.g., thalamus, globus palidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; each additional array 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 a single electrode array 61886 - ... with connection to 2 or more electrode arrays 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 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 (e.g., 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 (i.e., cranial nerve, peripheral nerve, sacral 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 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 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 time 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 time with physician or other qualified health care professional (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 - 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 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

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
Reviewed	04/22/2021	Codes updated
Reviewed	03/24/2022	No changes
Reviewed	03/30/2023	No changes
Updated	03/11/2024	Removed codes that have been deleted (95974, 95975, 95978, 95979). Formatting changes, added hyperlinks to NCD and TMPPM, beginning and ending note sections updated to align with CMS requirements and business entity change.

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. BSWHP 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 BSWHP 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.doc Hayes 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>.

***Note**:*
Health Maintenance Organization (HMO) products are offered through Scott and White Health Plan dba Baylor Scott & White Health Plan, and Scott & White Care Plans dba Baylor Scott & White Care Plan. Insured PPO and EPO products are offered through Baylor Scott & White Insurance Company. Scott and White Health Plan dba Baylor Scott & White Health Plan serves as a third-party administrator for self-funded employer-sponsored plans. Baylor Scott & White Care Plan and Baylor Scott & White Insurance Company are wholly owned subsidiaries of Scott and White Health Plan. These companies are referred to collectively in this document as Baylor Scott & White Health Plan.

RightCare STAR Medicaid plans are offered through Scott and White Health Plan in the Central Managed Care Service Area (MRSA) and STAR and CHIP plans are offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSAs.