MEDICAL POLICY

POLICY TITLE	DEEP BRAIN STIMULATION
POLICY NUMBER	MP 1.042

Clinical Benefit:	**☒ Minimize safety risk or concern.** **☒ Minimize harmful or ineffective interventions.** **☐ Assure appropriate level of care.** **☐ Assure appropriate duration of service for interventions.** **☐ Assure that recommended medical prerequisites have been met.** **☐ Assure appropriate site of treatment or service.**
Effective Date:	**10/1/2024**

I. POLICY

Unilateral deep brain stimulation of the thalamus may be considered **medically necessary** in individuals with disabling, medically unresponsive tremor (see policy guidelines) due to essential tremor or Parkinson's disease.

Bilateral deep brain stimulation of the thalamus may be considered **medically necessary** in individuals with disabling, medically unresponsive (see policy guidelines) tremor in both upper limbs due to essential tremor or Parkinson disease.

Unilateral or bilateral deep brain stimulation of the globus pallidus or subthalamic nucleus may be considered **medically necessary** in the following individuals:

- Those with Parkinson's disease with **all** of the following:
  - a good response to levodopa; **AND**
  - motor complications not controlled by pharmacologic therapy; **AND**
  - one of the following:
    - a minimum score of 30 points on the motor portion of the Unified Parkinson Disease Rating Scale when the patient has been without medication for approximately 12 hours; **OR**
    - Parkinson disease for at least 4 years
- Individuals age greater than seven (7) years with chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia and cervical dystonia (torticollis).

Bilateral deep brain stimulation of the anterior nucleus of the thalamus may be considered **medically necessary** for the treatment of medically refractory epilepsy when all the following criteria are met:

- Age 18 years and older; **AND**

- Individuals with partial onset seizures with or without secondary generalizations to tonic-clonic activity; **AND**
- Individuals have had no response to 3 or more antiepileptic medications; **AND**
- The individual as an average of 6 or more seizures a month, over the 3 most recent months prior to DBS implantation (with no more than 30 days between seizures)
    - Note: DBS has not been evaluated in individuals with less frequent seizures.

Deep brain stimulation is considered **investigational** for the following (but not limited to) list of indications, as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with these procedures:

- Other movement disorders including, but not limited to, multiple sclerosis and post-traumatic dyskinesia and tardive dyskinesia; **or**
- Treatment of chronic cluster headaches; **or**
- Psychiatric disorders or neurologic disorders including, but not limited to Tourette syndrome, depression, and obsessive-compulsive disorder, anorexia nervosa, alcohol addiction, Alzheimer disease, and chronic pain.

Deep brain stimulation is **contraindicated** in patients with the following conditions:

- Patients who are not good surgical risks because of unstable medical problems or because of cardiac pacemakers;
- Patients who have medical conditions that require repeated magnetic resonance imaging (MRI);
- Patients who have dementia that may interfere with the ability to cooperate;
- Patients who have had botulinum toxin injections within the last six months.

POLICY GUIDELINES

Disabling, medically unresponsive tremor is defined as all of the following:

- Tremor causing significant limitation in daily activities;
- Inadequate control by maximal dosage of medication for at least 3 months before implant.

Cross-reference:

MP 1.069 Spinal Cord and Dorsal Root Ganglion Stimulation

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

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FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies .

III. DESCRIPTION/BACKGROUND

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Deep Brain Stimulation

Deep brain stimulation (DBS) involves the stereotactic placement of an electrode into the brain (i.e., hypothalamus, thalamus, globus pallidus, or subthalamic nucleus). The electrode is initially attached to a temporary transcutaneous cable for short-term stimulation to validate treatment effectiveness. Several days later, the patient returns for permanent subcutaneous surgical implantation of the cable and a radiofrequency-coupled or battery-powered programmable stimulator. The electrode is typically implanted unilaterally on the side corresponding to the most severe symptoms. However, use of bilateral stimulation using two electrode arrays has also been investigated in patients with bilateral, severe symptoms. After implantation, noninvasive programming of the neurostimulator can be adjusted to the patient's symptoms. This feature may be important for patients with Parkinson disease (PD), whose disease may progress over time, requiring different neurostimulation parameters. Setting the optimal neurostimulation parameters may involve the balance between optimal symptom control and appearance of adverse effects of neurostimulation, such as dysarthria, disequilibrium, or involuntary movements.

Regulatory Status

In 1997, the Activa® Tremor Control System (Medtronic) was cleared for marketing by the U.S. Food and Drug Administration (FDA) for deep brain stimulation. The Activa® Tremor Control System consists of an implantable neurostimulator, a deep brain stimulator lead, an extension that connects the lead to the power source, a console programmer, a software cartridge to set electrical parameters for stimulation, and a patient control magnet, which allows the patient to turn the neurostimulator on and off or change between high and low settings.

The FDA labeled indications for Activa® were originally limited to unilateral implantation for the treatment of tremor, but the indications have evolved over time. In 2002, the FDA labeled indications were expanded to include bilateral implantation as a treatment to decrease the symptoms of advanced Parkinson disease not controlled by medication. In 2003, the labeled indications were further expanded to include "…unilateral or bilateral stimulation of the internal globus pallidus or subthalamic nucleus 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." In 2018, the deep brain stimulation system received an expanded indication as an adjunctive therapy for epilepsy (P960009 S318). Other deep brain stimulation systems are described in Table 1.

System	Manufacturer	FDA Product Code	PMA or HDE	Approval Date	Indications

Activa® Deep Brain Stimulation Therapy System	Medtronic	MBX	P96009	1997	Unilateral or bilateral stimulation of the internal globus pallidus or subthalamic nucleus for symptoms of Parkinson disease or primary dystonia
Reclaim® DBS Therapy for Obsessive Compulsive Disorder	Medtronic		H050003	2009	Bilateral stimulation of the anterior limb of the internal capsule for severe obsessive-compulsive disorder
Brio Neurostimulation System	St. Jude Medical	NHL	P140009	2015	Parkinsonian tremor (subthalamic nucleus) and essential tremor (thalamus)
Infinity DBS	St. Jude Medical	PJS	P140009	2016	Parkinsonian tremor
BenignVercise DBS System	Boston Scientific	NHL	P150031	2017	Moderate-to-advanced levodopa-responsive PD inadequately controlled with medication alone

Medtronic DBS System for Epilepsy	Medtronic	MBX	P9600009-S219	2018	Expanded indication for epilepsy with bilateral stimulation of the anterior nucleus of the thalamus
Percept PC Deep Brain Stimulation	Medtronic	MHY	P9600009-S	2000	Records brain signals while delivering therapy for PD or primary dystonia
Vercise Genus DBS System	Boston Scientific	NHL	P150031-S034	2021	Stimulation of the subthalamic nucleus and globus pallidus for PD
SenSight Directional Lead System	Medtronic	MHY	P960009	2021	Unilateral or bilateral stimulation for PD, tremor, dystonia, and epilepsy

DBS: deep brain stimulation; HDE: humanitarian device exemption; OCD: obsessive-compulsive disorder; PD: Parkinson disease; PMA: premarket approval

IV. RATIONALE

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Summary of Evidence

For individuals who have essential tremor or tremor in Parkinson disease who receive deep brain stimulation of the thalamus, the evidence includes a systematic review and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The systematic review (a TEC Assessment) concluded that there was sufficient evidence that deep brain stimulation of the thalamus results in clinically significant tremor suppression and that outcomes after deep brain stimulation were at least as good as thalamotomy. Subsequent studies reporting long-term follow-up have supported the conclusions of the TEC Assessment and found that tremors were effectively controlled 5 to 6 years after deep brain stimulation. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have symptoms (e.g., speech, motor fluctuations) associated with Parkinson disease (advanced or >4 years in duration with early motor symptoms) who receive deep brain stimulation of the globus pallidus interna or subthalamic nucleus, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. One of the systematic reviews (a TEC Assessment) concluded that studies evaluating deep brain stimulation of the globus pallidus interna or subthalamic nucleus have consistently demonstrated clinically significant improvements in outcomes (e.g., neurologic function). Other systematic reviews have also found significantly better outcomes after deep brain stimulation than after a control intervention. An RCT in patients with levodopa-responsive Parkinson disease of at least 4 years in duration and uncontrolled motor symptoms found that quality of life at 2 years was significantly higher when deep brain stimulation was provided in addition to medical therapy. Meta-analyses of RCTs comparing deep brain stimulation of the globus pallidus interna with deep brain stimulation of the subthalamic nucleus have reported mixed findings and have not shown that 1 type of stimulation is superior to the other. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have primary dystonia who receive deep brain stimulation of the globus pallidus interna or subthalamic nucleus, the evidence includes systematic reviews, RCTs, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A pooled analysis of 24 studies, mainly uncontrolled, found improvements in motor scores and disability scores after 6 months and at last follow-up (mean, 32 months). Both double-blind RCTs found that severity scores improved more after active than after sham stimulation. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have tardive dyskinesia or tardive dystonia who receive deep brain stimulation, the evidence includes a systematic review, an RCT and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The systematic review found an improvement in symptom severity with deep brain stimulation, but the authors noted some cases of symptom worsening or lack of improvement. All of the 14 included studies had small sample sizes (range, 2 to 22 patients). The RCT did not report statistically significant improvement in the dystonia severity outcomes, or the secondary outcomes related to disability and quality of life, but these may have been underpowered. Additional studies, especially RCTs or other controlled studies, are needed. The evidence is

insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have epilepsy who receive deep brain stimulation, the evidence includes systematic reviews, RCTs, and many observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Two RCTs with more than 15 patients were identified. The larger RCT evaluated anterior thalamic nucleus deep brain stimulation and reported that deep brain stimulation had a positive impact on seizure frequency during some parts of the blinded trial phase, but not others, and a substantial number of adverse events (in >30% of patients). There were no differences between groups in 50% responder rates, Liverpool Seizure Severity Scale, or Quality of Life in Epilepsy scores. A 7-year open-label follow-up of the RCT included 66% of implanted patients; reasons for missing data were primarily related to adverse events or dissatisfaction with the device. Reduction in seizure frequency continued to improve during follow-up among the patients who continued follow-up. The smaller RCT (n=16) showed a benefit with deep brain stimulation. Many small observational studies reported fewer seizures compared with baseline, however, without control groups, interpretation of these results is limited. Additional trials are required to determine the impact of deep brain stimulation on patient outcomes.

For individuals who have Tourette syndrome who receive deep brain stimulation, the evidence includes observational studies, RCTs, and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Two RCTs with 15 or more patients have been reported. One RCT found differences in severity of Tourette syndrome for active versus sham at 3 months while the other RCT did not. Neither study demonstrated improvements in comorbid symptoms of obsessive-compulsive disorder or depression. Both studies reported high rates of serious adverse events. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have cluster headaches or facial pain who receive deep brain stimulation, the evidence includes a randomized crossover study and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. In the RCT, the between-group difference in response rates did not differ significantly between active and sham stimulation phases. Additional RCTs or controlled studies are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have treatment-resistant depression who receive deep brain stimulation, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A number of case series and several prospective controlled trials evaluating deep brain stimulation have been published. Two RCTs of deep brain stimulation in the subgenual cingulate cortex and ventral striatum/ventral capsule were terminated for futility. Another RCT of stimulation of the same brain area (ventral striatum/ventral capsule) did not find a statistically significant difference between groups in the primary outcome (clinical response), and adverse psychiatric events occurred more frequently in the treatment group than in the control group. More recently, a controlled crossover trial randomized patients to sham or active stimulation of the anterior limb of the internal capsule after a year of open-label stimulation. There was a greater reduction in symptom scores after

active stimulation, but only in patients who were responders in the open-label phase. Stimulation of the subcallosal (subgenual) cingulate was evaluated in a 2019 sham-controlled within-subject study that found prolonged response in 50% of patients and remission in 30% of patients with treatment-resistant depression. Deep brain stimulation for patients with major depressive disorder who have failed all other treatment options is an active area of research, but the brain regions that might prove to be effective for treatment-resistant depression have yet to be established. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have obsessive-compulsive disorder who receive deep brain stimulation, the evidence includes RCTs and meta-analyses. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Among the RCTs on deep brain stimulation for obsessive-compulsive disorder, only 1 has reported an outcome of clinical interest (therapeutic response rate), and that trial did not find a statistically significant benefit for deep brain stimulation compared with sham treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have multiple sclerosis who receive deep brain stimulation, the evidence includes RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. One RCT with 10 multiple sclerosis patients is insufficient evidence on which to draw conclusions about the efficacy of deep brain stimulation in this population. Additional trials are required. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have anorexia nervosa, alcohol addiction, Alzheimer disease, Huntington's disease, or chronic pain who receive deep brain stimulation, the evidence includes case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. RCTs are needed to evaluate the efficacy of deep brain stimulation for these conditions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

V. DEFINITIONS

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DYSARTHRIA is difficult, poorly articulated speech, resulting from interference in the control and execution over the muscles of speech, usually caused by damage to a central or peripheral motor neuron.

GLOBUS PALLIDUS is the smaller and more medial part of the lentiform nucleus of the brain, separated from the putamen by the lateral medullary lamina and divided into external and internal portions closely connected to the thalamus and mesencephalon.

HYPOTHALAMUS is a part of the diencephalon that serves as the chief region for integration of sympathetic and parasympathetic activities.

SUBCUTANEOUS refers to beneath the skin.

SUBTHALAMUS is a part of the diencephalon that serves as a correlation center for optic and vestibular impulses relayed to the globus pallidus.

THALAMUS is one of a pair of large oval structures made of gray matter and forming most of the lateral walls of the third ventricle of the brain. It relays sensory and motor information, excluding smell, to the cerebral cortex.

UNIFIED PARKINSON DISEASE RATING SCALE (UPDRS) is a rating tool to follow the longitudinal course of Parkinson's disease.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross' medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

Procedure codes								
61850	61863	61864	61867	61868	61880	61885	61886	61888
95970	95971	95972	95983	95984	C1767	C1778	C1820	C1883
L8679	L8680	L8681	L8682	L8683	L8685	L8686	L8687	L8688
L8689	L8695							

POLICY TITLE	DEEP BRAIN STIMULATION
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ICD-10-CM Diagnosis Codes	Description
G20.A1	Parkinson's disease without dyskinesia, without mention of fluctuations
G20.A2	Parkinson's disease without dyskinesia, with fluctuations
G20.B1	Parkinson's disease with dyskinesia, without mention of fluctuations
G20.B2	Parkinson's disease with dyskinesia, with fluctuations
G20.C	Parkinsonism, unspecified
G21.0	Malignant neuroleptic syndrome
G21.11	Neuroleptic induced parkinsonism
G21.19	Other drug induced secondary parkinsonism
G21.2	Secondary parkinsonism due to other external agents
G21.3	Postencephalitic parkinsonism
G21.4	Vascular parkinsonism
G21.8	Other secondary parkinsonism
G21.9	Secondary parkinsonism, unspecified
G24.01	Drug induced subacute dyskinesia
G24.02	Drug induced acute dystonia
G24.09	Other drug induced dystonia
G24.1	Genetic torsion dystonia
G24.2	Idiopathic nonfamilial dystonia
G24.3	Spasmodic torticollis
G24.4	Idiopathic orofacial dystonia
G24.8	Other dystonia
G24.9	Dystonia, unspecified
G25.0	Essential tremor
G25.2	Other specified forms of tremor
G40	Epilepsy and recurrent seizures
G40.0	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset
G40.1	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures
G40.2	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures
G40.3	Generalized idiopathic epilepsy and epileptic syndromes
G40.4	Other generalized epilepsy and epileptic syndromes
G40.8	Other epilepsy and recurrent seizures
G40.841	KCNQ2-related epilepsy, not intractable, with status epilepticus
G40.842	KCNQ2-related epilepsy, not intractable, without status epilepticus
G40.843	KCNQ2-related epilepsy, intractable, with status epilepticus

ICD-10-CM Diagnosis Codes	Description
G40.844	KCNQ2-related epilepsy, intractable, without status epilepticus
G40.9	Epilepsy, unspecified
G40.C01	Lafora progressive myoclonus epilepsy, not intractable, with status epilepticus
G40.C09	Lafora progressive myoclonus epilepsy, not intractable, without status epilepticus
G40.C11	Lafora progressive myoclonus epilepsy, intractable, with status epilepticus
G40.C19	Lafora progressive myoclonus epilepsy, intractable, without status epilepticus
M43.6	Torticollis

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82. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.63, Deep Brain Stimulation. May 2024*

X. POLICY HISTORY

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MP 1.042	**12/21/2020 Consensus Review**. Policy statement unchanged. References reviewed. Updated background and rationale.
	06/24/2021 Consensus Review. No change to policy statement. FDA table updated. References reviewed and updated. Product Variations updated.
	09/02/2022 Consensus Review. No change to policy statement. FDA table updated. Rationale, References updated. Coding reviewed.
	05/22/2023 Minor Review. Moved epilepsy from INV to MN with additional criteria. Updated background and referenced. Added associated G40 ICD-10 codes.
	10/01/2023 Administrative Update. New diagnosis codes added, one code removed from policy from new code review.
	07/05/2024 Consensus Review. No changes to policy statement. References updated. Coding reviewed, no changes.
	9/12/2024 Administrative Update. 4 new diagnosis codes added, effective 10/1/2024.

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