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:	**6/1/2026**

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).

Adaptive deep brain stimulation for Parkinson disease is considered **investigational** (see Policy Guidelines), as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with the procedure.

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

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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.

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

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

Parkinson disease is a complex condition and might entail a complex system of care particularly when the disease has advanced. Adaptive DBS (aDBS) is a closed-loop system incorporating feedback from brain signals to dynamically adjust stimulation parameters. It is a more personalized approach to treatment of advanced disease and holds promise for reducing stimulation duration and energy consumption while treating motor related issues such as dyskinesia. The FDA submission for aDBS by Medtronic was as an optional programming feature for Parkinson's Disease in existing devices. It was not studied in bilaterally implanted neurostimulators, and the labeling instructs not to use aDBS with more than one implanted neurostimulator.

Cross-Reference:
MP 1.156 Responsive Neurostimulation for the Treatment of Refractory Focal Epilepsy

PRODUCT VARIATIONS

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

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 .

DESCRIPTION/BACKGROUND

Deep Brain Stimulation

Deep brain stimulation 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, the use of bilateral stimulation using 2 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, 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 approved by the U.S. Food and Drug Administration (FDA) through the pre-market approval process 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 7 years of age or above." In 2018, the deep brain stimulation system received an expanded indication as an adjunctive therapy for epilepsy (P960009-S219). 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
BrainSense™ Adaptive Deep Brain Stimulation	Medtronic	MHY	P960009	2025	Automatically adjusted therapeutic stimulation to maximize reduction of PD symptoms

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

RATIONALE

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 randomized controlled trials (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 with symptoms associated with Parkinson disease who receive adaptive deep brain stimulation of the globus pallidus interna or subthalamic nucleus, the evidence includes one RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. There is currently one ongoing RCT assessing the feasibility and efficacy of adaptive deep brain stimulation (aDBS) for control of Parkinson disease symptoms. One RCT assessed the feasibility and efficacy of adaptive deep brain stimulation for control of Parkinson disease symptoms. The primary efficacy outcome measured "On" time without dyskinesia, with success rates of 78.9% for single-threshold aDBS and 91% for dual-threshold aDBS. Safety analysis showed that overall 78.8% of patients experienced adverse events, 56.5% had device-related events, and 17.6% had serious adverse events, including one participant with 2 severe device-related injuries. The evidence is insufficient 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 an RCT and case series. Relevant outcomes are symptoms,

functional outcomes, quality of life, and treatment-related morbidity. 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 first RCT (N=110) 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 second RCT (N=16) showed a benefit with deep brain stimulation. Many 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 systematic review, randomized crossover study, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The systematic review included an individual patient data meta-analysis of 34 patients, showing a significant reduction in pain intensity at 3 months following deep brain stimulation for chronic facial pain; data for follow-up beyond 3 months were not eligible for statistical analysis. In an RCT of 11 patients with severe, refractory, chronic cluster headache, 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 meta-analyses of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Among the RCTs on deep brain stimulation for obsessive-compulsive disorder included in meta-analyses, 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 other neurologic or psychiatric disorders who receive deep brain stimulation, the evidence includes a number of nonrandomized studies or RCTs in patients with multiple sclerosis, chronic pain, or alcohol use disorder. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. One RCT with 10 multiple sclerosis patients, 2 RCTs in patients with chronic pain, and 1 RCT in patients with treatment-refractory alcohol use disorder is insufficient evidence on which to draw conclusions about the efficacy of deep brain stimulation in these populations. Additional trials are required. For individuals who have anorexia nervosa, Alzheimer disease, Huntington disease, or chronic pain who receive deep brain stimulation, the evidence includes case series; 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.

DEFINITIONS

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.

DISCLAIMER

Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as permitted by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These policies are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.

CODING INFORMATION

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	95983	95984						

Covered when medically necessary:

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HCPCS								
C1767	C1778	C1820	C1883	L8679	L8680	L8681	L8682	L8683
L8685	L8686	L8687	L8688	L8689	L8695			

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
G24.02	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
M43.6	Torticollis

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POLICY HISTORY

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 10/01/2024.
	07/01/2025 Major Review. Added INV criteria for adaptive brain stimulation.

	Moved epilepsy from MN to INV. Updated background, rationale, references. Coding reviewed.
	10/09/2025 Administrative Update. Removed Benefit Variations Section and updated Disclaimer.
	02/11/2026 Consensus Review. Updated policy guidelines and references. Removed 2 analysis procedure codes from policy as they are not applicable to the brain.

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