MEDICAL POLICY

POLICY TITLE	DEEP BRAIN STIMULATION
POLICY NUMBER	MP-1.042

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I. POLICY

Unilateral deep brain stimulation of the thalamus may be considered **medically necessary** in patients 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 patients 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 patients:

- 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
- Patients age greater than seven (7) years with chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia and cervical dystonia (torticollis).

Deep brain stimulation is considered **investigational** for the following (but not limited to) list of indications, as there is insufficient evidence to support a 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 chronic pain, and epilepsy.

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; **or**
- 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 Top

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

FEP PPO: FEP PPO - Refer to FEP Benefit Brochure for information:
https://www.fepblue.org/benefit-plans/benefit-plans-brochures-and-forms

III. DESCRIPTION/BACKGROUND Top

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.

Essential Tremor and PD

DBS has been investigated as an alternative to permanent neuroablative procedures, such as thalamotomy and pallidotomy. DBS has been most thoroughly investigated as an alternative to thalamotomy for unilateral control of essential tremor (ET) and tremor associated with PD. More recently, there has been research interest in the use of DBS of the globus pallidus or subthalamic nucleus as a treatment of other parkinsonian symptoms, such as rigidity, bradykinesia, and akinesia. Another common morbidity associated with PD is the occurrence of motor fluctuations, referred to as "on and off" phenomena, related to the maximum effectiveness of drugs (i.e., "on" state) and the nadir response during drug troughs (i.e., "off" state). In addition, levodopa, the most commonly used anti-Parkinson drug, may be associated with disabling drug-induced dyskinesias. Therefore, the optimal pharmacologic treatment of PD may involve a balance between optimal effects on PD symptoms and the appearance of drug-induced dyskinesias. The effect of DBS on both PD symptoms and drug-induced dyskinesias has also been studied.

Primary and Secondary Dystonia

DBS has also been investigated in patients with primary and secondary dystonia, defined as a neurologic movement disorder characterized by involuntary muscle contractions, which force certain parts of the body into abnormal, contorted, and painful movements or postures. Dystonia can be classified according to age of onset, bodily distribution of symptoms, and cause. Age of onset can occur during childhood or during adulthood. Dystonia can affect certain portions of the body (focal dystonia and multifocal dystonia) or the entire body (generalized dystonia). Torticollis is an example of a focal dystonia. Primary dystonia is defined when dystonia is the only symptom unassociated with other pathology. Treatment options for dystonia include oral or injectable medications (i.e., botulinum toxin) and destructive surgical or neurosurgical interventions (i.e., thalamotomies or pallidotomies) when conservative therapies fail. Secondary dystonia is a dystonia brought on by an inciting event, such as a stroke, trauma, or drugs. Tardive dystonia is a form of drug-induced secondary dystonia.

Cluster Headaches

DBS has been investigated in patients with chronic cluster headaches. Cluster headaches occur as episodic attacks of severe pain lasting from 30 minutes to several hours. The pain is usually unilateral and localized to the eye, temple, forehead, and side of the face. Autonomic symptoms that occur with cluster headaches include ipsilateral facial sweating, flushing, tearing, and

rhinorrhea. Cluster headaches occur primarily in men and have been classified as vascular headaches associated with, among other things, high blood pressure, smoking, and alcohol use. However, the exact pathogenesis of cluster headaches is uncertain. Positron emission tomography scanning and magnetic resonance imaging have shown the hypothalamic region may be important in the pathogenesis of cluster headaches. Alterations in hormonal or serotonergic function may also play a role. Treatment of cluster headaches includes pharmacologic interventions for acute episodes and prophylaxis, sphenopalatine ganglion blockade, and surgical procedures such as percutaneous sphenopalatine ganglion radiofrequency rhizotomy, and gamma knife radiosurgery of the trigeminal nerve.

Neurologic and Psychiatric Disorders

The role of DBS in treatment of other treatment-resistant neurologic and psychiatric disorders, particularly epilepsy, Tourette syndrome, major depressive disorders, and obsessive-compulsive disorder, is also being investigated. Ablative procedures are irreversible and, though they have been refined, remain controversial treatments for intractable illness. Interest has shifted to neuromodulation through DBS of nodes or targets within neural circuits involved in these disorders. Currently, a variety of target areas are being studied.

Regulatory Status

In 1997, the Activa® Tremor Control System (Medtronic) was cleared for marketing by the U.S. Food and Drug Administration (FDA) for DBS. 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 original FDA-labeled indications for Activa® were limited to unilateral implantation of the device for the treatment of tremor, but, in 2002, FDA-labeled indications were expanded to include bilateral implantation as a treatment to decrease the symptoms of advanced PD 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." This latter indication was cleared for marketing by FDA through the humanitarian device exemption process. In 2017, the indications for PD were modified to include "adjunctive therapy in reducing some of the symptoms in individuals with levodopa-responsive Parkinson's Disease of at least 4 years' duration that are not adequately controlled with medication."

In 2009, the Reclaim® device (Medtronic), a DBS device, was cleared for marketing by FDA through the humanitarian device exemption process for the treatment of severe obsessive-compulsive disorder.

In 2014, the Brio Neurostimulation System (now called Infinity; St. Jude Medical Neuromodulation) was cleared for marketing by FDA for the treatment of Parkinsonian tremor.

In 2016, the St. Jude Medical's Infinity DBS device with directional leads was approved by FDA. The directional leads enable the clinician to "steer" current to different parts of the brain. This tailored treatment reduces side effects. The Infinity system can be linked to Apple's iPod Touch and iPad Mini.

In December 2017, a second system with directional leads, the Vercise Deep Brain Stimulation System (Boston Scientific), was approved by FDA. This system is to be used as an adjunctive therapy from reducing motor symptoms of moderate-to-advanced levodopa-responsive PD inadequately controlled with medication alone.

FDA product code: MHY.

IV. RATIONALE Top

Summary of Evidence

For individuals who have essential tremor or tremor in PD who receive DBS 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 DBS of the thalamus results in clinically significant tremor suppression and that outcomes after DBS 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 DBS. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have symptoms (e.g., speech, motor fluctuations) associated with PD (advanced or >4 years in duration with early motor symptoms) who receive DBS of the globus pallidus interna (GPi) or subthalamic nucleus (STN), 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 DBS of the GPi or STN have consistently demonstrated clinically significant improvements in outcomes (e.g., neurologic function). Other systematic reviews have also found significantly better outcomes after DBS than after a control intervention. An RCT in patients with levodopa-responsive PD of at least 4 years in duration and uncontrolled motor symptoms found that quality of life at 2 years was significantly higher when DBS was provided in addition to medical therapy. Meta-analyses of RCTs comparing DBS of the GPi with DBS of the STN have reported mixed findings and have not shown that one type of stimulation is clearly superior to the other. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have primary dystonia who receive DBS of the GPi or STN, the evidence includes systematic reviews, an RCT, 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). A double-blind RCT found that severity scores improved more after active than after sham stimulation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have tardive dyskinesia or tardive dystonia who receive DBS, the evidence includes case series, one of which included a double-blind comparison of outcomes when the DBS device was turned on versus off. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Few studies were identified and they had small sample sizes (range, 9-19 patients). Additional studies, especially RCTs or other controlled studies, are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have epilepsy who receive DBS, the evidence includes two systematic reviews of RCTs and many observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Two RCTs were identified. The larger reported that DBS had a positive impact during some parts of the blinded trial phase but not others, and a substantial number of adverse events (in >30% of patients). The smaller RCT (N=16) showed a benefit with DBS. 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 DBS on patient outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have multiple sclerosis who receive DBS, the evidence includes an 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 DBS in this population. Additional trials are required. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have Tourette syndrome who receive DBS, the evidence includes crossover RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Several small (≤15 patients) crossover trials and a 2015 meta-analysis have suggested that DBS may improve outcomes in patients with Tourette syndrome. However, the optimal target of the brain for DBS is unknown, so additional controlled studies in larger numbers of patients are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have cluster headaches or facial pain who receive DBS, 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 randomized study, 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 the effects of the technology on health outcomes.

For individuals who have treatment-resistant depression who receive DBS, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The only double-blind, parallel-group RCT in patients with depression did not find that DBS significantly increased the response rate compared with sham; two other RCTs were stopped due to futility. A crossover controlled trial randomized patients to active or to sham stimulation 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; these findings might not be generalizable. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have obsessive-compulsive disorder who receive DBS, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Among the RCTs on DBS for obsessive-compulsive disorder, only one has reported the outcome of greatest clinical interest (therapeutic response rate), and that trial did not find a statistically significant benefit for DBS compared with sham treatment. The evidence is insufficient to determine the effects of the technology on health

For individuals who have anorexia nervosa, alcohol addiction, Alzheimer disease, Huntington disease, or chronic pain who receive DBS, 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 DBS for these conditions. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's 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 BlueCross' Provider Services or Member Services. Capital BlueCross 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:

CPT Codes®								
61850	61863	61864	61867	61868	61880	61885	61886	61888
95970	95971	95972	95983	95984				

HCPCS Codes	Description
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system

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C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)
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, nonrechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable 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

ICD-10-CM Diagnosis Codes	Description
G20	Parkinson's disease
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
G24.5	Blepharospasm
G24.8	Other dystonia
G24.9	Dystonia, unspecified
G25.0	Essential tremor
G25.2	Other specified forms of tremor
M43.6	Torticollis

IX. REFERENCES

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X. POLICY HISTORY

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MP 1.042	**CAC 12/2/03**
	CAC 4/27/04
	CAC 6/28/05
	CAC 5/30/06
	CAC 11/28/06
	CAC 11/27/07
	CAC 1/27/09
	CAC 1/26/10 Added neurologic disorders, Tourette syndrome, epilepsy and tardive dyskinesia as investigational. References updated.
	CAC 7/26/11 Adopt BCBSA; For unilateral deep brain stimulation of the thalamus, removed the requirement of inadequate control by maximal dosage of levodopa for at least three months before implant for Parkinson's disease. An FEP variation was added.
	CAC 8/28/12 Consensus review; no changes to policy statements, references updated. FEP variation revised.
	Admin 3/28/13 Coding changes
	CAC 7/30/2013 Consensus review list
	CAC 3/25/14 Consensus review. References updated. .Anorexia nervosa, alcohol addiction, and chronic pain were added to the list of examples of psychiatric and neurological disorders considered investigational. Rationale added.
	CAC 3/24/15 Minor review. Added statement indicating bilateral stimulation of the thalamus is medically necessary for bilateral tremor. Updated references and rationale. Coding reviewed.
	CAC 3/29/16 Consensus review. No changes to the policy statements. References updated. Coding reviewed.

POLICY TITLE	DEEP BRAIN STIMULATION
POLICY NUMBER	MP-1.042

	Admin update 1/1/17 Product variation section reformatted
	CAC 3/28/17 Consensus review. The word "upper" as added the medically necessary statement on DBS for medically unresponsive tremor due to essential tremor or Parkinson disease to provide clarification that the statement refers to both upper limbs. Rationale and references updated. Coding reviewed.
	CAC 7/25/17 Minor revision. In the medically necessary statement on unilateral or bilateral deep brain stimulation of the globus pallidus or subthalamic nucleus "OR Parkinson disease for at least 4 years" was added to the medically necessary criteria for use in Parkinson disease. Alzheimer disease added as another example of an investigational indication. Background, rationale and references updated. Coding reviewed.
	1/1/18 Admin Update: Medicare variations removed from Commercial Policies.
	2/23/18 Consensus review. No changes to the policy statements. References reviewed**.**
	1/1/19 Admin Update: Removed deleted codes 95974-95979. Added new codes 95983 & 95984 effective 1/1/19.
	2/11/19 Consensus review. No changes to the policy statements. Background and references updated. Rationale revised.
	2/18/20 Consensus review. Policy statement unchanged. References updated. Coding updated.

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