DEEP BRAIN STIMULATION

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.

Description:

Deep brain stimulation (DBS) involves the stereotactic placement of an electrode into the brain to improve the symptoms of selected brain disorders i.e., essential tremor and Parkinson disease. A “test” electrode is placed to determine if electrical stimulation will suppress the symptoms. If suppressed, a permanent electrode is placed. DBS has been investigated for the treatment of a variety of other neurologic and psychiatric disorders including alcohol addiction, Alzheimer disease, anorexia nervosa, chronic pain, cluster headaches, depression, dystonia, epilepsy, multiple sclerosis, dyskinesias, obsessive-compulsive disorder (OCD) and Tourette syndrome.
DEEP BRAIN STIMULATION (cont.)

Definitions:

Disabling:
Causes significant limitation in activities of daily living and is not controlled by adequate dosage of medication for at least 3 months before implant.

Essential Tremor:
A brain disorder involving rhythmic tremors of the voluntary muscles when an individual is moving or trying to move. There is no identifiable cause.

Medication-refractory:
Inadequate control by maximum dosage of medication for at least 3 months before implantation; drug resistant.

Microelectrode Mapping:
Intraoperative microelectrode mapping (neurophysiologic mapping or testing) required for precise placement of electrodes during deep brain stimulation.

Parkinson Disease (PD):
A brain disorder involving tremors and movement difficulty, i.e., rigidity, akinesia, bradykinesia, dyskinesia, and lack of coordination. PD may affect one or both sides of the body.

Primary Dystonia:
Dystonia is a brain disorder involving involuntary muscle contractions that force certain parts of the body into contorted, sometimes painful movements or postures. Dystonia can affect certain portions of the body (focal dystonia and multifocal dystonia) or the entire body (generalized dystonia). Primary dystonia is defined when dystonia is the only symptom unassociated with other pathology.
DEEP BRAIN STIMULATION (cont.)

Criteria:

For neurostimulation for refractory epilepsy, see BCBSAZ Medical Coverage Guideline #O942, “Responsive Neurostimulation for Refractory Partial Epilepsy”.

Parkinson Disease:

- Unilateral deep brain stimulation of the thalamus for treatment of Parkinson disease is considered medically necessary with documentation of ALL of the following:
  1. Symptoms are disabling and medication-refractory (see Definitions section)
  2. No unstable medical problems or cardiac pacemaker
  3. No medical condition that requires repeated MRIs
  4. No dementia that may interfere with the ability to cooperate
  5. No botulinum toxin injections within the last 6 months

- Bilateral deep brain stimulation of the thalamus for treatment of Parkinson disease is considered medically necessary with documentation of ALL of the following:
  1. Disabling, medically unresponsive tremor in both upper limbs (see Definitions section)
  2. No unstable medical problems or cardiac pacemaker
  3. No medical condition that requires repeated MRIs
  4. No dementia that may interfere with the ability to cooperate
  5. No botulinum toxin injections within the last 6 months

- Unilateral or bilateral deep brain stimulation of the globus pallidus or subthalamic nucleus for treatment of Parkinson disease is considered medically necessary with documentation of ALL of the following:
  1. Good response to levodopa
  2. Minimal score of 30 points on the motor portion of the Unified Parkinson Disease Rating Scale when individual has been without medication for about 12 hours
  3. Motor complications not controlled by pharmacologic therapy
  4. No unstable medical problems or cardiac pacemaker
  5. No medical condition that requires repeated MRIs
  6. No dementia that may interfere with the ability to cooperate
  7. No botulinum toxin injections within the last 6 months
DEEP BRAIN STIMULATION (cont.)

Criteria: (cont.)

Essential Tremor:

- Unilateral deep brain stimulation for treatment of essential tremor is considered *medically necessary* with documentation of **ALL** of the following:

  1. Symptoms are disabling and medication-refractory (see Definitions section)
  2. Symptoms have been present for 3 months or greater
  3. No dementia that may interfere with the ability to cooperate
  4. Brain MRI is normal or shows no evidence of structural abnormalities
  5. No prior intracranial surgery at targeted area
  6. Stimulation is to the thalamus, globus pallidus or subthalamic nucleus area of the brain

- Bilateral deep brain stimulation of the thalamus for treatment of essential tremor is considered *medically necessary* with documentation of **ALL** of the following:

  1. Disabling, medically unresponsive tremor in both upper limbs (see Definitions section)
  2. No unstable medical problems or cardiac pacemaker
  3. No medical condition that requires repeated MRIs
  4. No dementia that may interfere with the ability to cooperate
  5. No botulinum toxin injections within the last 6 months

Primary Dystonia:

Unilateral or bilateral deep brain stimulation for treatment of primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis), is considered *medically necessary* with documentation of the following:

  1. Individual is 7 years of age or older
  2. Symptoms are chronic and medication-refractory (see Definitions section)
  3. Stimulation is to the globus pallidus or subthalamic nucleus area of the brain
DEEP BRAIN STIMULATION (cont.)

Criteria: (cont.)

Microelectrode Mapping:

- Intraoperative microelectrode mapping is required and considered medically necessary for precise placement of electrodes during deep brain stimulation.

Other:

- Unilateral or bilateral deep brain stimulation for all other indications not previously listed or if above criteria not met is considered experimental or investigational based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome.

These indications include, but are not limited to:

- Cluster headaches
- Multiple sclerosis
- Post-traumatic dyskinesia
- Tardive dyskinesia
- Treatment of other psychiatric or neurologic disorders, e.g., Tourette syndrome, depression, obsessive compulsive disorder, epilepsy, anorexia nervosa, alcohol addiction, chronic pain

Resources:

Literature reviewed 05/24/16. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

DEEP BRAIN STIMULATION (cont.)

**Resources**: (cont.)

FDA Product Approval Database for Activa® Parkinson’s Control System:

- FDA-approved indication: For the bilateral stimulation of the internal globus pallidus (Gpi) or the subthalamic nucleus (STN) as adjunctive therapy in reducing some of the symptoms of advanced, levodopa-responsive Parkinson’s disease that are not adequately controlled with medication.

For the unilateral thalamic stimulation for the suppression of tremor in the upper extremity in patients who are diagnosed with essential tremor or parkinsonian tremor not adequately controlled by medications and where the tremor constitutes a significant functional disability.

FDA Humanitarian Device Exemption for Activa Tremor Control System:

- The HDE allows Medtronic to market the above device for the 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.

FDA Humanitarian Device Exemption for Reclaim™:

- The HDE allows Medtronic to market the above device for the bilateral stimulation of the anterior limb of the internal capsule, AIC, as an adjunct to medications and as an alternative to anterior capsulotomy for treatment of chronic, severe, treatment-resistant obsessive compulsive disorder (OCD) in adult patients who have failed at least three selective serotonin reuptake inhibitors (SSRIs).