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.

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.

Description:

Deep brain stimulation (DBS) involves the unilateral or bilateral stereotactic placement of an electrode into the brain to improve the symptoms of selected brain disorders. A “test” electrode is placed to determine if electrical stimulation will suppress the symptoms. If suppressed, a permanent electrode is placed. Only the Activa® Tremor Control System is FDA-approved. DBS has been investigated as a treatment of cluster headaches, multiple sclerosis, dyskinesias, and certain psychiatric and neurological disorders.

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.

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

Parkinson's 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.
MEDICAL COVERAGE GUIDELINES

SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 08/01/08
LAST REVIEW DATE: 06/27/12
LAST CRITERIA REVISION DATE: 06/28/11

DEEP BRAIN STIMULATION (cont.)

Definitions:

Primary Dystonia:
A brain disorder involving involuntary muscle contractions that force certain parts of the body into contorted, sometimes painful movements or postures.

Disabling:
Causes significant limitation in activities of daily living.

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

Criteria:

Parkinson’s Disease:

- Unilateral or bilateral deep brain stimulation of the thalamus for treatment of Parkinson’s 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

- Unilateral or bilateral deep brain stimulation of the globus pallidus or subthalamic nucleus area of the brain for treatment of Parkinson’s 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 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 or bilateral deep brain stimulation for treatment of essential tremor is considered *medically necessary* with documentation of **ALL** of the following:

  1. Symptoms have been present for 3 months or greater
  2. Symptoms are disabling and medication-refractory (see Definitions section)
  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

**Primary Dystonia:**

- Unilateral or bilateral deep brain stimulation for treatment of primary dystonia* 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

* Includes generalized and/or segmental dystonia, hemidystonia and cervical dystonia (torticollis)

**Microelectrode Mapping:**

- Intraoperative microelectrode mapping is **required** and considered *medically necessary* for precise placement of electrodes during deep brain stimulation.
DEEP BRAIN STIMULATION (cont.)

Criteria: (cont.)

Other:

- Unilateral or bilateral deep brain stimulation for all other indications not previously listed 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

Resources:


DEEP BRAIN STIMULATION (cont.)

Resources: (cont.)


DEEP BRAIN STIMULATION (cont.)

Resources: (cont.)


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

- FDA-approved indication: 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.

FDA Humanitarian Device Exemption for Medtronic Activa® Dystonia Therapy 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.