DEEP BRAIN STIMULATION FOR ESSENTIAL TREMOR AND PARKINSON'S DISEASE
Medicare National Coverage Determination (NCD) 160.24 Checklist

NCD 160.24	**Patient Name:**	**MR:**

Effective Date: For services performed on or after 4/1/2003

Deep brain stimulation **(DBS)** refers to high-frequency electrical stimulation of anatomic regions deep within the brain utilizing neurosurgically implanted electrodes on one (unilateral) or both (bilateral) sides of the brain. The targeted areas are: the thalamic ventralis intermedius nucleus **(VIM)**, subthalamic nucleus **(STN)** and globus pallidus interna **(GPi)**.
Essential tremor **(ET)** is a progressive, disabling tremor most often affecting the hands and at times head, voice and legs. For patients who do not respond or cannot tolerate medications, thalamic VIM DBS may be helpful for symptomatic relief of tremor.
Parkinson's disease **(PD)** is an age-related progressive neurodegenerative disorder involving the loss of dopaminergic cells in the substantia nigra of the midbrain. The disease is characterized by tremor, rigidity, bradykinesia and progressive postural instability. For patients who become unresponsive to medical treatments and/or have intolerable side effects from medications, DBS for symptom relief may be considered.

GENERAL REQUIREMENTS

□	Must be a Food and Drug Administration (FDA) approved devices for DBS or devices used in accordance with FDA approved protocols governing Category B Investigational Device Exemption (IDE) DBS clinical trials.
□	Neurosurgeons must be properly trained in the procedure, have experience with the surgical management of movement disorders, including DBS therapy, and have experience performing stereotactic neurosurgical procedures.
□	Operative teams must have training and experience with DBS systems, including knowledge of anatomical and neurophysiological characteristics for localizing the targeted nucleus, surgical and/or implantation techniques for the DBS system, and operational and functional characteristics of the device.
□	Physicians specializing in movement disorders must be involved in both patient selection and post-procedure care.
□	Hospital must have: (a) brain imaging equipment (MRI and/or CT) for pre-operative stereotactic localization and targeting of the surgical site(s); (b) operating rooms with all necessary equipment for stereotactic surgery; and (c) support services necessary for care of patients undergoing this procedure and any potential complications arising intraoperatively or postoperatively.

Safety Notes:
- Patients who undergo DBS implantation should not be exposed to diathermy (deep heat treatment including shortwave diathermy, microwave diathermy and ultrasound diathermy) or any type of MRI which may adversely affect the DBS system or adversely affect the brain around the implanted electrodes.
- The DBS should be performed with extreme caution in patients with cardiac pacemakers or other electronically controlled implants which may adversely affect or be affected by the DBS system.

Diagnosis Coding: The following diagnosis codes are covered:
- ICD-10-CM G20 - Parkinson's disease
- ICD-10-CM G25.0 - Essential tremor
- ICD-10-CM G25.2 - Other specified form of tremor

ICD-10-PCS and HCPCS Procedure Codes can be found in the Medicare Claims Processing Manual, Chapter 32 Section 50

COVERAGE INDICATIONS

Thalamic VIM DBS (unilateral or bilateral) IS considered medically necessary when all of the criteria below is met.

□	Diagnosis of either: • Essential tremor based on postural or kinetic tremors of hand(s) without other neurologic signs, OR • Idiopathic Parkinson's Disease (presence of at least 2 cardinal PD features (tremor, rigidity or bradykinesia)) which is of a tremor-dominant form; and
□	Marked disabling tremor of at least level 3 or 4 on the Fahn-Tolosa-Marin Clinical Tremor Rating Scale (or equivalent scale) in the extremity intended for treatment, causing significant limitation in daily activities despite optimal medical therapy; and
□	Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.

STN or GPi DBS (unilateral or bilateral) IS considered medically necessary when all of crteria below is met.

□	Diagnosis of Parkinson's Disease based on the presence of at least 2 cardinal PD features (tremor, rigidity or bradykinesia); and
□	Advanced idiopathic Parkinson's Disease as determined by the use of Hoehn and Yahr stage or Unified Parkinson's Disease Rating Scale (UPDRS) part III motor subscale; and
□	L-dopa responsive with clearly defined "on" periods; and
□	Persistent disabling Parkinson's symptoms or drug side effects (e.g., dyskinesias, motor fluctuations, or disabling "off" periods) despite optimal medical therapy; and
□	Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.

NONCOVERED INDICATIONS

The DBS is NOT covered for ET or PD patients with any of the following:
1. Non-idiopathic Parkinson's disease or "Parkinson's Plus" syndromes.
2. Cognitive impairment, dementia or depression which would be worsened by or would interfere with the patient's ability to benefit from DBS.
3. Current psychosis, alcohol abuse or other drug abuse.
4. Structural lesions such as basal ganglionic stroke, tumor or vascular malformation as etiology of the movement disorder.
5. Previous movement disorder surgery within the affected basal ganglion.
6. Significant medical, surgical, neurologic or orthopedic co-morbidities contraindicating DBS surgery or stimulation.

Checklist completed by: **Date:**