

# Deep Brain Stimulation for Essential Tremor and Parkinson's Disease

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[Instructions for Use](#)

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## Related Medicare Advantage Policy Guideline

- [Deep Brain Stimulation for Essential Tremor and Parkinson's Disease \(NCD 160.24\)](#)

## Coverage Guidelines

Deep brain stimulation for essential tremor and Parkinson's Disease is covered when Medicare criteria are met.

### Covered Deep Brain Stimulation (DBS)

Unilateral or bilateral thalamic ventralis intermedius nucleus (VIM) deep brain stimulation (DBS) for the treatment of essential tremor (ET) and/or Parkinsonian tremor and unilateral or bilateral subthalamic nucleus (STN) or globus pallidus interna (GPi) DBS for the treatment of Parkinson's Disease (PD) are covered only under the following conditions:

- DBS devices are considered to be reasonable and necessary if they are 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.
- For thalamic VIM DBS to be considered reasonable and necessary, patients must meet all of the following criteria:
  - Diagnosis of ET based on postural or kinetic tremors of hand(s) without other neurologic signs, or diagnosis of idiopathic PD (presence of at least 2 cardinal PD features (tremor, rigidity or bradykinesia) which is of a tremor-dominant form.
  - 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.
  - Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.
- For STN or GPi DBS to be considered reasonable and necessary, patients must meet all of the following criteria:
  - Diagnosis of PD based on the presence of at least 2 cardinal PD features (tremor, rigidity or bradykinesia).
  - Advanced idiopathic PD as determined by the use of Hoehn and Yahr stage or Unified Parkinson's Disease Rating Scale (UPDRS) part III motor subscale.
  - L-dopa responsive with clearly defined "on" periods.
  - Persistent disabling Parkinson's symptoms or drug side effects (e.g., dyskinesias, motor fluctuations, or disabling "off" periods) despite optimal medical therapy.
  - Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings

## Non-Covered Deep Brain Stimulation (DBS)

DBS is not reasonable and necessary and is not covered for ET or PD patients with any of the following:

- Non-idiopathic Parkinson's Disease or "Parkinson's Plus" syndromes.
- Cognitive impairment, dementia or depression, which would be worsened by or would interfere with the patient's ability to benefit from DBS.
- Current psychosis, alcohol abuse or other drug abuse.
- Structural lesions such as basal ganglionic stroke, tumor or vascular malformation as etiology of the movement disorder.
- Previous movement disorder surgery within the affected basal ganglion.
- Significant medical, surgical, neurologic or orthopedic co-morbidities contraindicating DBS surgery or stimulation

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. 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.
- For DBS lead implantation to be considered reasonable and necessary, providers and facilities must meet all of the following criteria:
  - 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 medical centers must have:
    - Brain imaging equipment (MRI and/or CT) for pre-operative stereotactic localization and targeting of the surgical site(s);
    - Operating rooms with all necessary equipment for stereotactic surgery; and
    - Support services necessary for care of patients undergoing this procedure and any potential complications arising intraoperatively or postoperatively

Refer to the [National Coverage Determination \(NCD\) for Deep Brain Stimulation for Essential Tremor and Parkinson's Disease \(160.24\)](#) (Accessed May 5, 2021)

## Definitions

**Deep Brain Simulation (DBS):** Refers to high-frequency electrical stimulation of anatomic regions deep within the brain utilizing neurosurgically implanted electrodes. These DBS electrodes are stereotactically placed within targeted nuclei on one (unilateral) or both (bilateral) sides of the brain. There are currently three targets for DBS – the thalamic ventralis intermedius nucleus (VIM), subthalamic nucleus (STN) and globus pallidus interna (GPi). [Medicare Claims Processing Manual, Chapter 32, §50 – Deep Brain Stimulation for Essential Tremor and Parkinson's Disease.](#) (Accessed May 5, 2021)

**Essential Tremor (ET):** A progressive, disabling tremor most often affecting the hands. ET may also affect the head, voice and legs. The precise pathogenesis of ET is unknown. While it may start at any age, ET usually peaks within the second and sixth decades. Beta-adrenergic blockers and anticonvulsant medications are usually the first line treatments for reducing the severity of tremor. Many patients, however, do not adequately respond or cannot tolerate these medications. In these medically refractory ET patients, thalamic VIM DBS may be helpful for symptomatic relief of tremor. [Medicare Claims Processing Manual, Chapter 32, §50 – Deep Brain Stimulation for Essential Tremor and Parkinson's Disease.](#) (Accessed May 5, 2021)

**Parkinson's Disease (PD):** 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. Dopaminergic medication is typically used as a first line treatment for reducing the primary symptoms of PD.

However, after prolonged use, medication can become less effective and can produce significant adverse events such as dyskinesias and other motor function complications. For patients who become unresponsive to medical treatments and/or have intolerable side effects from medications, DBS for symptom relief may be considered. [Medicare Claims Processing Manual, Chapter 32. §50 – Deep Brain Stimulation for Essential Tremor and Parkinson’s Disease](#). (Accessed May 5, 2021)

## Policy History/Revision Information

Date	Summary of Changes
05/18/2021	<ul style="list-style-type: none"><li data-bbox="337 384 946 415">• Routine review; no change to coverage guidelines</li><li data-bbox="337 415 886 447">• Archived previous policy version MCS024.01</li></ul>

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The benefit information in this Coverage Summary is based on existing national coverage policy; however, Local Coverage Determinations (LCDs) may exist and compliance with these policies are required where applicable.

There are instances where this document may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG). In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)).

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