DEEP BRAIN STIMULATION FOR ESSENTIAL TREMOR AND PARKINSON’S DISEASE (NCD 160.24)

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INSTRUCTIONS FOR USE

This Policy Guideline is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates for health care services submitted on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450), or their electronic comparative. The information presented in this Policy Guideline is believed to be accurate and current as of the date of publication.

This Policy Guideline provides assistance in administering health benefits. All reviewers must first identify member eligibility, any federal or state regulatory requirements, Centers for Medicare and Medicaid Services (CMS) policy, the member specific benefit plan coverage, and individual provider contracts prior to use of this Policy Guideline. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document may differ greatly from the standard benefit plan upon which this Policy Guideline is based. In the event of a conflict, the member specific benefit plan document supersedes this Policy Guideline. Other Policies and Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

UnitedHealthcare follows Medicare coverage guidelines and regularly updates its Medicare Advantage Policy Guidelines to comply with changes in CMS policy. UnitedHealthcare encourages physicians and other healthcare professionals to keep current with any CMS policy changes and/or billing requirements by referring to the CMS or your local carrier website regularly. Physicians and other healthcare professionals can sign up for regular distributions for policy or regulatory changes directly from CMS and/or your local carrier. This Policy Guideline is provided for informational purposes. It does not constitute medical advice.

POLICY SUMMARY

Overview
Essential tremor (ET) is a progressive, disabling action tremor (also referred to as a kinetic or postural tremor) which most often affects the hands during sustained arm extension or during voluntary motion such as writing or pouring. ET may also affect the head, voice, and legs and affects more than one million patients in the U.S. Although ET may start at any age, there appears to be a bimodal distribution peaking in the second and sixth decades. ET affects men and women equally and while its precise pathogenesis is unknown, it does occur genetically in some families as an autosomal dominant trait.

Pharmacotherapy is the first line treatment of ET and may improve function by reducing the severity of tremor. However, certain patients do not adequately respond to or cannot tolerate these medications. Thalamic Deep Brain Stimulation (DBS) may be helpful for carefully selected individuals with marked tremor causing significant functional disability that is refractory to optimal medical therapy.

Parkinson's disease (PD) is an age-related neurodegenerative disorder, characterized by tremor, rigidity, bradykinesia (gradual loss of spontaneous movement) and progressive postural instability. PD affects up to one million Americans. The primary underlying abnormality in PD is the progressive loss of dopamine-producing cells in the brain, leading to an imbalance of dopamine and acetylcholine, the normal neurotransmitters in the corpus striatum. The most common form, idiopathic PD, begins most often between ages forty five to sixty five, with average onset at age fifty-eight. The cause of PD remains unknown, although proposed theories include the role of genetic and certain environmental factors.
For patients who become unresponsive to pharmacological treatments and/or have intolerable drug side effects, DBS may be helpful; DBS requires the stereotactic placement of an indwelling electrode in the brain. This treatment for PD supports observations that high-frequency stimulation of the affected neurons induces functional inhibition in target regions of the brain. DBS thus simulates the effect of an ablative surgical lesion but, unlike lesioning surgery, DBS adjusts the implanted electrode can be re-positioned (or removed). The mechanism of action remains unknown. Possible mechanisms include release of local inhibitory neurotransmitters, depolarization blockade, or jamming of abnormal neuron firing patterns.

The device currently used for DBS is the Active® system developed by Medtronic, Inc. (Minneapolis, MN). The system consists of several implantable and nonimplantable components (listed below), including a quadripolar electrode (four contact sites arranged along the distal edge) which is stereotactically implanted into the targeted structure. Stimulation parameters, including electrode contact site selection, stimulation pulse amplitude, frequency, and width adjusts to optimize symptom relief.

Guidelines
Medicare will cover 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 subthalamus (STN) or globus pallidus interna (GPI) DBS for the treatment of Parkinson's disease (PD) only under the following conditions:

Medicare will only consider DBS devices 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 three or four 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 two 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

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 worsens or interferes 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

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.

### APPLICABLE CODES

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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<th>CPT Code</th>
<th>Description</th>
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<tr>
<td>61885</td>
<td>Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array</td>
</tr>
<tr>
<td>61886</td>
<td>Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays</td>
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<tr>
<td>61888</td>
<td>Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; each additional array (List separately in addition to primary procedure)</td>
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<td>95961</td>
<td>Functional cortical and subcortical mapping by stimulation and/or recording of electrodes on brain surface, or of depth electrodes, to provoke seizures or identify vital brain structures; initial hour of attendance by a physician or other qualified health care professional</td>
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<tr>
<td>95962</td>
<td>Functional cortical and subcortical mapping by stimulation and/or recording of electrodes on brain surface, or of depth electrodes, to provoke seizures or identify vital brain structures; each additional hour of attendance by a physician or other qualified health care professional (List separately in addition to code for primary procedure)</td>
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<td>95970</td>
<td>Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming</td>
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<tr>
<td>95971</td>
<td>Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (i.e., peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming</td>
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<tr>
<td>95978</td>
<td>Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, battery status, electrode selectability and polarity, impedance and patient compliance measurements), complex deep brain neurostimulator pulse generator/transmitter, with initial or subsequent programming; first hour</td>
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CPT Code | Description
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95979 | Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, battery status, electrode selectability and polarity, impedance and patient compliance measurements), complex deep brain neurostimulator pulse generator/transmitter, with initial or subsequent programming; each additional 30 minutes after first hour (List separately in addition to code for primary procedure)

ICD-10 Diagnosis Code | Description
--- | ---
G20 | Parkinson's disease
G25.0 | Essential tremor
G25.2 | Other specified forms of tremor

ICD-10 Procedure Code | Description
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00H00MZ | Insertion of neurostimulator lead into brain, open approach
00H03MZ | Insertion of neurostimulator lead into brain, percutaneous approach
00H04MZ | Insertion of neurostimulator lead into brain, percutaneous endoscopic approach
00H60MZ | Insertion of neurostimulator lead into cerebral ventricle, open approach
00H63MZ | Insertion of neurostimulator lead into cerebral ventricle, percutaneous approach
00H64MZ | Insertion of neurostimulator lead into cerebral ventricle, percutaneous endoscopic approach

REFERENCES

CMS National Coverage Determinations (NCDs)
NCD 160.24 Deep Brain Stimulation for Essential Tremor and Parkinson's Disease
Reference NCDs: NCD 160.18 Vagus Nerve Stimulation; NCD 160.7 Electrical Nerve Stimulators

CMS Benefit Policy Manual
Chapter 14; § 10 Coverage of Medical Devices
Chapter 15; § 260 Ambulatory Surgical Center Services

CMS Claims Processing Manual
Chapter 12; § 90.3 Physicians’ Services Performed in Ambulatory Surgical Centers (ASC)
Chapter 14; § 10 General ASC Information
Chapter 20; § 110 General Billing Requirements - for DME, Prosthetics, Orthotic Devices, and Supplies
Chapter 32; § 50 Deep Brain Stimulation for Essential Tremor and Parkinson’s Disease

MLN Matters
Article MM8531, Calendar Year (CY) 2014 Update for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule

UnitedHealthcare Commercial Policies
Deep Brain Stimulation

Others
Technology Assessment: Bilateral Deep Brain Stimulation (DBS) Of The Subthalamic Nucleus (STN) Or The Globus Pallidus Interna (Gpi) For Treatment Of Advanced Parkinson's Disease, CMS Website

GUIDELINE HISTORY/REVISION INFORMATION

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<th>Date</th>
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<td>05/10/2017</td>
<td>• Annual review; administrative updates</td>
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