Deep Brain Stimulation for Essential Tremor and Parkinson's Disease (NCD 160.24)

Guideline Number: MPG070.06
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Terms and Conditions

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Policy Summary

See Purpose

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 effects 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 lessoning 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 Activa® system developed by Medtronic, Inc. (Minneapolis, MN). The system consists of several implantable and nonimplantable components, 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 are then adjusted 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 subthalamic nucleus (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 procedure and/or diagnosis 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.

CPT Code	Description
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays
61888	Revision or removal of cranial neurostimulator pulse generator or receiver
95961	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
95962	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)
95970	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
95971	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
95978	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 (Deleted 12/31/2018; see 95983)

CPT Code	Description
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 (Deleted 12/31/2018; see 95984)
95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional (Effective 01/01/2019)
95984	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure) (Effective 01/01/2019)

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 32; § 50 Deep Brain Stimulation for Essential Tremor and Parkinson's Disease

CMS Transmittal(s)

Transmittal 2243, Change Request 11134, Dated February 1, 2019 (International Classification of Diseases, 10th Revision (ICD-10) and Other Coding Revisions to National Coverage Determination (NCDs))

UnitedHealthcare Commercial Policy

Deep Brain and Cortical Stimulation

Other(s)

Decision Memo for Deep Brain Stimulation for Parkinson's Disease (CAG-00124N), CMS Website
National Coverage Analysis (NCA) for Deep Brain Stimulation for Parkinson's Disease (CAG-00124N), CMS Website
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

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes
04/01/2021	Template Update • Reformatted policy; transferred content to new template
05/13/2020	Supporting Information • Updated *References* section to reflect the most current information • Archived previous policy version MPG070.05

Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

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 member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided.

UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.