
Program Memorandum Intermediaries/Carriers

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

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CHANGE REQUEST 2553

SUBJECT: Deep Brain Stimulation for Essential Tremor and Parkinson's Disease

Deep brain stimulation (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).

Essential tremor (ET) is 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.

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. 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.

Effective on or after April 1, 2003, Medicare will cover *unilateral or bilateral thalamic VIM DBS* for the treatment of ET and/or Parkinsonian tremor and *unilateral or bilateral STN or GPi DBS* for the treatment of PD only under the following conditions:

1. 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.
2. For thalamic VIM DBS to be considered reasonable and necessary, patients must meet all of the following criteria:
 - a. Diagnosis of essential tremor (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.
 - b. 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.
 - c. Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.

3. For STN or GPi DBS to be considered reasonable and necessary, patients must meet all of the following criteria:
 - a. Diagnosis of PD based on the presence of at least 2 cardinal PD features (tremor, rigidity or bradykinesia).
 - b. 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.
 - c. L-dopa responsive with clearly defined "on" periods.
 - d. Persistent disabling Parkinson's symptoms or drug side effects (e.g., dyskinesias, motor fluctuations, or disabling "off" periods) despite optimal medical therapy.
 - e. 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:

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.

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:

1. Neurosurgeons must: (a) be properly trained in the procedure; (b) have experience with the surgical management of movement disorders, including DBS therapy; and (c) have experience performing stereotactic neurosurgical procedures.
2. 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.
3. Physicians specializing in movement disorders must be involved in both patient selection and post-procedure care.

4. Hospital medical centers 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.

Part A Intermediary Billing Procedures

This procedure can be two fold. Implantation of the electrodes is performed in a hospital inpatient setting. Implantation of the pulse generator can be performed in an outpatient department.

Part A Payment Methods

Payment for the inpatient procedure is under Diagnostic Related Group (DRG). The outpatient procedure is outpatient prospective payment system. For critical access hospitals (CAH), the inpatient stay is on reasonable cost and the outpatient procedures are also based on reasonable cost.

Applicable Bill Types

11X, 12X, 13X, 83X, 85X

Applicable Revenue Codes

Revenue codes for implementation can be performed in a number of revenue centers within a hospital such as operating room (360) or clinic (510). The codes to report the pulse generator and/or electrodes are 270, 278, 279.

For CAHs that choose method II, use revenue code 98X for the professional component only.

Intermediary and Carrier Billing Procedures

Allowable Covered Diagnosis Codes

Deep Brain Stimulation is covered for the following ICD-9-CM diagnosis codes:

332.0 - Parkinson's disease, with paralysis agitans

333.1 – Essential and other specified forms of tremor

Allowable Covered Procedure Codes

The following procedure codes may be present:

02.93 – Implantation of intracranial neurostimulator, encompasses the component parts of the surgery that include tunneling to protect the wiring and the initial creation of a pocket for the insertion of the electrical unit into the chest wall

86.09 – Other incision of skin and subcutaneous tissue, to reflect the creation of a pocket for the battery device

86.99 – Other operations on skin and subcutaneous tissue, for the tunneling of the wire connectors

HCPCS Coding

The following HCPCS codes are available for use when billing for covered deep brain stimulation:

- E0752 Implantable Neurostimulator Electrode, Each
- E0756 Implantable Neurostimulator Pulse Generator
- 61862 Twist drill, burr hole, craniectomy for stereotactic implantation of one neurostimulator array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray)
- 61880 Revision or removal of intracranial neurostimulator electrodes
- 61885 Incision and subcutaneous placement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
- 61886 Incision and subcutaneous placement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to two 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 physician attendance
- 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 physician attendance (List separately in addition to code for primary procedure) (Use 95962 in conjunction with code 95961)
- 95970 Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and 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, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
- 95971 Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple brain, spinal cord, or peripheral (i.e., peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
- 95972 Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex brain, spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour
- 95973 Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex brain, spinal cord, or peripheral (except cranial nerve); complex brain, spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, additional 30 minutes after hour (List separately in addition to code for primary procedure) (Use 95973 in conjunction with code 95972)

Ambulatory Surgical Centers

The following HCPCS codes are approved for billing in Ambulatory Surgical Centers:

- 61885 Incision and subcutaneous placement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array - ASC Payment Group 02
- 61888 Revision or removal of cranial neurostimulator pulse generator or receiver - ASC Payment Group 01

NOTE: Pulse generator is payable in an ASC; implantation of electrodes are not.

Carrier Claims Requirements

Follow the general instruction for preparing claims as indicated in the electronic claims specifications contained at www.cms.hhs.gov/providers/edi/default.asp, as discussed in the Medicare Carriers Manual (MCM) Part 3 §3023.6A or the addenda to Medicare Intermediary Manual (MIM) Part 3 §3600, and as reported in the Health Insurance Portability And Accountability Act electronic transactions program memoranda issued by CMS. Instructions for the limited number of claims submitted on paper are located in MCM Part 4 §2010 or MIM Part 3 §3604.

Carrier Payment Requirements

Payment and pricing information will be on the Medicare Physician Fee Schedule Database (MPFSDB). Pay for Medicare Part B claims on the basis of the MPFS. Deductible and coinsurance apply. Claims from physicians or other practitioners where assignment was not taken are subject to the Medicare limiting charge (refer to MCM Part 3, chapter VII, §7555 for more information).

Claims Editing for Intermediaries and Carriers

We do not require nationwide standard system claims processing edits for pre and post payment review of claim(s) at this time. However, carriers and intermediaries may create local claims processing edits for the requirements listed above.

Remittance Advice Notice for Intermediaries and Carriers

Use appropriate existing remittance advice reason and remark codes at the line level to express the specific reason if you deny payment for DBS. If denying services as furnished before April 1, 2003, use existing ANSI X 12-835 claim adjustment reason code 26 "Expenses incurred prior to coverage" at the line level.

Medicare Summary Notice (MSN) Messages for Intermediaries and Carriers

Use the following MSN messages where appropriate:

If a claim for DBS is denied because the service was performed prior to April 1, 2003, use the MSN message:

"This service was not covered by Medicare at the time you received it." (MSN Message 21.11)

The Spanish version of the MSN message should read:

"Este servicio no estaba cubierto por Medicare cuando usted lo recibió." (MSN Message 21.11)

Provider Notification

Contractors should notify providers of this new national coverage in their next regularly scheduled bulletin, on their Web site within 2 weeks, and in routinely scheduled training sessions.

The effective date for this PM is April 1, 2003.

The implementation date for this PM is April 1, 2003.

These instructions should be implemented within your current operating budget.

This PM may be discarded after April 1, 2004.

If you have any questions, contact your regional office.