
CMS Manual System

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CHANGE REQUEST 2553

I. SUMMARY OF CHANGES: Manualization of Deep Brain Stimulation

NEW/REVISED MATERIAL - EFFECTIVE DATE: Not Applicable

*IMPLEMENTATION DATE: Not Applicable

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS:

(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
N	50 – Deep Brain Stimulation for Essential Tremor and Parkinson’s Disease
N	50.1 – Coverage
N	50.2 – Billing Requirements
N	50.2.1 – Part A Intermediary Billing Procedures
N	50.3 – Payment Requirements
N	50.3.1 – Part A Payment Methods
N	50.3.2 – Bill Types
N	50.3.3 – Revenue Codes
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N	50.5 – Ambulatory Surgical Centers
N	50.6 – Claims Editing for Intermediaries
N	50.7 – Remittance Advice Notice for Intermediaries
N	50.8 – Medicare Summary Notices (MSN) Messages for Intermediaries
N	50.9 – Provider Notification

*III. FUNDING:

These instructions shall be implemented within your current operating budget.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

***Medicare contractors only**

Medicare Claims Processing Manual

Chapter 32 – Billing Instructions for Special Services

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50 – Deep Brain Stimulation for Essential Tremor and Parkinson’s Disease

(Rev. 128, 03-26-04)

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.

50.1 – Coverage Requirements

(Rev. 128, 03-26-04)

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.*

50.2 – Billing Requirements

(Rev. 128, 03-26-04)

50.2.1 – Part A Intermediary Billing Procedures

(Rev. 128, 03-26-04)

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.

50.3 - Payment Requirements

(Rev. 128, 03-26-04)

50.3.1 – Part A Payment Methods

(Rev. 128, 03-26-04)

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.

50.3.2 – Bill Types

(Rev. 128, 03-26-04)

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

50.3.3 – Revenue Codes

(Rev. 128, 03-26-04)

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.

50.4 – Allowable Codes

(Rev. 128, 03-26-04)

50.4.1 – Allowable Covered Diagnosis Codes

(Rev. 128, 03-26-04)

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

50.4.2 – Allowable Covered Procedure Codes

(Rev. 128, 03-26-04)

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

50.4.3 – Healthcare Common Procedural Coding System (HCPCS)

(Rev. 128, 03-26-04)

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)*

50.5 – Ambulatory Surgical Centers

(Rev. 128, 03-26-04)

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.

50.6 – Claims Editing for Intermediaries

(Rev. 128, 03-26-04)

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.

50.7 – Remittance Advice Notice for Intermediaries

(Rev. 128, 03-26-04)

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.

50.8 - Medicare Summary Notice (MSN) Messages for Intermediaries

(Rev. 128, 03-26-04)

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)

50.9 – Provider Notification

(Rev. 128, 03-26-04)

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.