Deep Brain Stimulation

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Definitions

Deep Brain Stimulation (DBS) refers to a neurosurgical procedure where deep brain structures are stimulated via implanted electrodes as a therapeutic maneuver for symptomatic relief in Parkinson's disease (PD), essential tremor (ET) and dystonia refractory to other treatments.

Currently, the therapeutic targets for DBS are selected regions of the thalamus (ventral intermediate nucleus [VIM]), the subthalamic nuclei (STN) and the globus pallidus internus (GPi).

Guideline

Members who have tried and failed three oral medications are eligible for coverage of unilateral or bilateral DBS with FDA-approved devices[1] as follows:

1. VIM DBS for the treatment of ET and/or Parkinsonian tremor.
2. STN or GPi DBS for the treatment of Parkinsonian tremor.
3. GPi DBS for the treatment of intractable primary dystonia (inclusive of generalized and/or segmental dystonia, hemidystonia and cervical dystonia).

[1] For Medicare members, devices must be FDA-approved or used in accordance with FDA-approved protocols governing Category B Investigational Device Exemption DBS clinical trials.

Thalamic VIM DBS — all: Diagnosis of ET based on postural or kinetic tremors of the hand(s) without other neurologic signs, or diagnosis of idiopathic PD (presence of at least 2 cardinal PD features [tremor, rigidity or bradykinesia] that are 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.	**STN or GPi DBS** — all: 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)[2] 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.[3] Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings. Members ≥ 8 years of age with intractable primary dystonia (inclusive of generalized and/or segmental dystonia, hemidystonia and cervical dystonia).

Utilization Guidelines

In the 1st month post electrode placement, intensive analysis and programming may be necessary to achieve optimal stimulus parameters. Monitoring with monthly follow-up visits may be warranted; therefore, the usual standard of care will be presumed to be:

1. 6 programming visits within 60 days of initial surgery.
2. 6 additional visits per year after the initial 60 days.

Conditions/Limitations

1. Prior to surgical selection, the member should have a multidisciplinary evaluation by persons with expertise in all the following:
    a. Stereotactic neurosurgery
2. Management of movement disorders:
    a. Neurophysiological monitoring
    b. Long-term postoperative care
3. The member should not be suffering from extensive brain atrophy, cognitive impairment, dementia or depression, which would be worsened by or would interfere with the member's ability to benefit from DBS.
4. There should be no focal lesion present at the target site, which might nullify the DBS result.

[2] Scale may be referenced at: http://www.movementdisorders.org/MDS-Files1/Resources/PDFs/MDS-UPDRS.pdf

[3] L-Dopa and at least one other medication should have been tried in the maximum tolerated dose unless a contraindication(s) existed that precluded its initial or continued use.

5. Sufficient residual motor function in the targeted extremity must be present to take advantage of the postoperative improvement in movement disorder.
6. The member should not be suffering from alcohol abuse or other drug abuse.
7. The member should not have structural lesions such as basal ganglionic stroke, tumor or vascular malformation as cause of the movement disorder.
8. The member should not have had previous movement disorder surgery within the affected basal ganglion.
9. The member should not have significant medical, surgical, neurologic or orthopedic co-morbidities contraindicating DBS surgery or stimulation.
10. Members 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.
11. DBS should be performed with extreme caution in members with cardiac pacemakers or other electronically controlled implants which may adversely affect or be affected by the DBS system.
12. The member, and/or the person responsible for the member, should be fully aware of the risks and benefits of the surgery, including the mortality and morbidity experience of the center and the performing surgeon.
13. 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.
14. 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.
15. Physicians specializing in movement disorders must be involved in both member selection and post-procedure care.
16. 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 members undergoing this procedure and any potential complications arising intraoperatively or postoperatively.

Exclusions

1. Non-idiopathic PD or “Parkinson’s Plus” syndrome is not a covered entity; only idiopathic PD will be covered.
2. DBS is not considered medically necessary for the treatment of any of the following, as there is insufficient evidence of effectiveness:
    a. Chronic cluster headache
    b. Degenerative disorders
    c. Depression as a primary diagnosis
    d. Drug-induced movement disorders
    e. Epilepsy
    f. Head tremors
    g. Infectious disease.
    h. Metabolic disorders
    i. Myasthenia gravis

j. Obsessive-compulsive disorder
k. Other tremor syndromes (e.g., multiple sclerosis, stroke)
l. Post trauma/surgical dystonia
m. Psychogenic dystonia
n. Tourette syndrome
o. Vegetative state
p. Voice tremors

Applicable Procedure Codes

61863	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; first array
61864	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; each additional array (List separately in addition to primary procedure)
61867	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; first array
61868	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; each additional array (List separately in addition to primary procedure)
61880	Revision or removal of intracranial neurostimulator electrodes
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 a single electrode array
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 (eg, 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 (ie, cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
95978	Electronic analysis of implanted neurostimulator pulse generator system (eg, 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
95979	Electronic analysis of implanted neurostimulator pulse generator system (eg, 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)
L8680	Implantable neurostimulator electrode, each. Revised Code
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement

	only
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only

Applicable ICD-10 Diagnosis Codes

G20	Parkinson's disease
G21.3	Postencephalitic parkinsonism
G21.4	Vascular parkinsonism
G24.1	Genetic torsion dystonia
G24.2	Idiopathic nonfamilial dystonia
G25.0	Essential tremor

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