

WellCare Health Plans, Inc.

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Clinical Coverage Guideline

WellCare Prescription Insurance, Inc.

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Deep Brain Stimulation for Essential Tremor and Parkinson's Disease

Guideline Number: HS-075

Original Effective Date: 1/12/2009

Revision Date: 1/29/2010

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

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DISCLAIMER

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APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

CLINICAL COVERAGE GUIDELINE

Unilateral or bilateral thalamic ventralis intermedius nucleus (VIM) deep brain stimulation (DBS) for the treatment of 333.1 Essential Tremor (ET) and/or 332.0 Parkinsonian tremor and unilateral or bilateral subthalamic nucleus (STN) or globus pallidus interna (GPi) DBS for the treatment of Parkinson's disease (PD) is considered medically necessary when the following criteria are met:

Thalamic VIM DBS is considered medically necessary when ALL of the following criteria are met:

- There is a diagnosis of ET based on postural or kinetic tremors of the hand(s) without other neurologic signs, or a diagnosis of idiopathic PD with the presence of at least two cardinal PD features (i.e. tremor, rigidity or bradykinesia) which is of a tremor-dominant form; **AND,**
- There is marked disabling tremor of a least level 3 or 4 on the Fahn-Tolosa-Marin Clinical Tremor Rating Scale in the extremity intended for treatment, causing significant limitation in daily activities despite optimal medical therapy; **AND,**
- There is a willingness and ability to cooperate during a conscious operative procedure, post-surgical evaluations, adjustments of medications and stimulator settings

STN or GPi DBS are considered medically necessary if ALL of the following criteria are met:

- A diagnosis of PD based on the presence of at least two cardinal PD features (see above); **AND,**
- 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; **AND,**
- L-dopa responsive with clearly defined "on" periods; **AND,**
- Persistent disabling Parkinson's symptoms or drug side effects (e.g. dyskinesias, motor fluctuations, or disabling "off" periods) despite optimal medical therapy; **AND,**
- There is a willingness and ability to cooperate during a conscious operative procedure, post-surgical

evaluations, adjustments of medications and stimulator settings

DBS is NOT medically necessary nor a covered benefit for members with ET and PD, if ANY of the following conditions are present:

- Non-idiopathic Parkinson's disease or "Parkinson's Plus" syndromes; **OR,**
- Cognitive impairment, dementia or depression, which would be worsened or interfere with the member's ability to benefit from DBS; **OR,**
- Current psychosis, alcohol abuse or other drug abuse; **OR,**
- Structural lesions such as basal ganglionic stroke, tumor or vascular malformation as etiology of the movement disorder; **OR,**
- Previous movement disorder surgery within the affected basal ganglion; **OR,**
- Significant medical, surgical, neurologic or orthopedic comorbidities contraindicating DBS surgery or stimulation.

NOTE: DBS devices are considered medically necessary if they are FDA approved or used in accordance with FDA approved protocols governing Category B Investigational Device Exemption (IDE) DBS clinical trials.

NOTE: 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.

NOTE: 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.

BACKGROUND

Essential tremor (ET), a common movement disorder, affects more than 1 million Americans and at least 1% of the adult population over the age of 40 years. This disorder has an insidious onset, with varying progression over time. Typical symptoms of ET include postural tremor of the outstretched upper limbs that is absent at rest, not worsened by movement, and not associated with extrapyramidal or cerebellar signs. Like ET, Parkinson's disease (PD) is a slowly progressing, chronic neurodegenerative disorder of unknown etiology. This disorder affects an estimated 1.5 million Americans, with approximately 40,000 new cases diagnosed each year. Although diagnostic criteria for PD vary among clinicians, PD is generally associated with the symptom complex of resting tremor, bradykinesia, and rigidity. In the advanced stages, PD leads to dementia and death. Most patients with movement disorders respond well to pharmacological treatments for extended periods of time; however, surgical treatments for PD and ET must be considered when these disorders become severe and medications fail or cause unacceptable side effects. Deep brain stimulation (DBS) is being investigated as an alternative to pallidotomy and thalamotomy for treatment of these movement disorders. DBS involves continuous, high frequency stimulation of the ventral intermediate nucleus (Vim) of the thalamus, the internal globus pallidus (GPi), or the subthalamic nucleus (STN), using electrodes implanted in one of these structures. Electrical stimulation of these areas of the brain simulates the effect of a surgical lesion, but, unlike pallidotomy and thalamotomy, DBS can be adjusted and reversed (from Hayes, 2004).

Deep Brain Stimulation Description

Deep Brain Stimulation (DBS) involves high-frequency electrical stimulation of a specific site in the ventral intermediate nucleus (Vim) of the pallidus, internal globus pallidus (GPi), or subthalamic nucleus (STN) of the brain using unilateral or bilateral electrodes that are connected to a pulse generator implanted in the chest. Proper placement of each electrode for DBS requires guidance by stereotactic localization. Sets of images acquired by magnetic resonance imaging (MRI) or by x-ray-based helical computed tomography (CT) are assembled into a coherent, detailed, three-dimensional model of the patient. To employ this model during surgery, magnetic or optical markers are attached to the patient at defined locations on a stereotactic frame. Local anesthesia prevents pain at the points where the frame contacts the skin of the patient. A computerized tracking system then collects data from an optical or magnetic sensor and displays the location of the site to be stimulated relative to the site of electrode insertion into the skull. The stereotactic guidance system also displays the

track the electrode should follow to reach the stimulation site. After a burr hole has been drilled in the skull to allow electrode insertion, stereotactic localization allows each electrode to be guided to within approximately 1 mm of the targeted site. The track for the deep brain electrode is prepared by inserting a probe approximately 10 mm from the target. Neurosurgeons then conduct test stimulations at frequencies over 100 Hz to evaluate tremor amplitude, diffusion of stimulation, the threshold for paresthesias, and the development of speech disturbances. In addition, some researchers apply electrical pulses at 2 to 4 Hz to study the diffusion of stimulation. Throughout the procedure, teleradiography may be used to confirm the electrode position. Once the optimal functional target has been identified and satisfactory stimulation obtained, the surgeon secures the permanent electrode to the skull using a plating system. The distal aspect of the electrode is then tunneled to a small incisional wound located behind the pinna of the ear, the wounds are closed in a fashion that allows electrode retrieval, and the stereotactic head frame is removed (from Hayes, 2004).

Provider and Facility Requirements

For DBS lead implantation to be considered medically necessary, providers and facilities must meet all of the following criteria:

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.

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:

- 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.

Hoehn and Yahn Scale

In the advanced stages, PD leads to dementia and death. The degree of disability is generally divided into five stages.

Stage I. Unilateral involvement only, usually with minimal or no functional impairment.

Stage II. Bilateral or midline involvement, without impairment of balance.

Stage III. First sign of impaired righting reflexes, evident by unsteadiness as patient turns or demonstrated when patient is pushed from standing equilibrium with the feet together and eyes closed. Functionally, the patient is somewhat restricted but is capable of activities of daily living (ADL). Disability is mild to moderate.

Stage IV. Fully developed severe disabling disease. The patient is still able to walk and stand unassisted but is markedly incapacitated.

Stage V. Confinement to wheelchair unless aided.

Unified Parkinson's Disease Rating Scale (UPDRS)

Total UPDRS consists of four parts.

Parts I, II, and III contain 44 questions each measured on a 5-point scale (0-4).

I. Mentation, behavior, and mood: intellectual impairment, thought disorder, motivation/initiative, depression

II. Activities of daily living (ADL): speech, salivation, swallowing, handwriting, cutting food, dressing, hygiene, turning in bed, falling, freezing, walking, tremor, sensory complaints

III. Motor examination: speech, facial expression, tremor at rest, action tremor, rigidity, finger taps, hand movements, hand pronation and supination, leg agility, arising from chair, posture, gait, postural stability, body bradykinesia

IV. Complications of therapy: dyskinesia-duration, dyskinesia-disability, dyskinesia-pain, early morning dystonia, "offs"-predictable, "offs"-unpredictable, "offs"-sudden, "offs"-duration, anorexia-nausea-vomiting, sleep disturbance, symptomatic orthostasis

CODING

CPT®* Codes

- 61863** 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), 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 (e.g., 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 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)
- 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 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 spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour

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

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.9-CM Procedure Codes

01.22 Removal of intracranial neurostimulator lead(s)

02.93 Implantation or replacement of intracranial neurostimulator lead(s)

86.05 Incision with removal of foreign body or device from skin and subcutaneous tissue

86.94 Insertion or replacement of single array neurostimulator pulse generator, not specified as rechargeable

86.95 Insertion or replacement of dual array neurostimulator pulse generator, not specified as rechargeable

86.96 Insertion or replacement of other neurostimulator pulse generator

HCPCS Level II Codes

C1767 Generator, neurostimulator (implantable), nonrechargeable

C1778 Lead, neurostimulator (implantable)

C1787 Patient programmer, neurostimulator

C1816 Receiver and/or transmitter, neurostimulator (implantable)

C1820 Generator, neurostimulator (implantable), with rechargeable battery and charging system

C1883 Adaptor/extension, pacing lead or neurostimulator lead (implantable)

C1897 Lead, neurostimulator test kit (implantable)

L8680 Implantable neurostimulator electrode, each

L8681 Patient programmer (external) for use with implantable programmable neurostimulator pulse generator

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

Covered ICD-9-CM Diagnosis Codes

332.0 Paralysis agitans; Parkinsonism or Parkinson's disease; idiopathic, primary, NOS

333.1 Essential Tremor; Benign, Familial, Postural

REFERENCES

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3. Hayes Directory, Deep Brain Stimulation for Parkinson's Disease and Essential Tremor, October 15, 2004 (updated 2008).
4. Pahwa, R, Factor, SA, Lyons, KE, Ondo, WG, Gronseth, G, Bronte-Stewart, H, Hallett, M, Miyasaki, J, Stevens, J, Weiner, WJ (2006). Practice Parameter: Treatment of Parkinson disease with motor fluctuations and dyskinesia (an evidence-based review): Report of the Quality Standards Subcommittee of the American Academy of Neurology, *Neurology*, 66, 983-995.
5. American Association of the Neurological Surgeons, and the Congress of Neurological Surgeons. Deep Brain Stimulation: Indications, Techniques, and Practice Parameters.
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