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Deep Brain Stimulation Policy

Indication/Usage:

Deep Brain Stimulation is an elective surgical procedure in which electrodes are implanted into certain brain areas. These electrodes, or leads, generate electrical impulses that control abnormal brain activity. The electrical impulses can also adjust for the chemical imbalances within the brain that cause various conditions. Stimulation of brain areas is controlled by a programmable generator that is placed under the skin in the upper chest. This procedure is utilized when medications are no longer effective for patients maintaining good quality of life.

The DBS system involves three distinct components:

- The electrode, or lead, is a thin, insulated wire inserted through a small opening in the skull and implanted into a specific brain area.
- The extension wire is also insulated and passed under the skin of the head, neck and shoulder, connecting the electrode to the internal pulse generator (IPG).
- The IPG is the third piece of the system and is usually implanted under the skin in the upper chest.

Medical Indications for Authorization Commercial Members

SummaCare considers unilateral deep brain stimulation for the thalamus medically necessary for treating the following conditions unresponsive to drug therapy.

- Essential Tremor
- Parkinson's disease

SummaCare considers deep brain stimulation of the subthalamic nucleus or globus pallidus medically necessary for the following conditions.

1. Members age 7 years or older with intractable dystonia including generalized, segmental, cervical dystonia and hemidystonia that is adequately controlled after a 3-month trial of medication management.

2. Members with Parkinson's Disease and All of the following
   - Good response to Levadopa
   - Motor complications unresponsive to medication management
   - A minimum score of 30 points on the motor portion of the United Parkinson's Disease Rating Scale when off medication for 12 hours.

3. Essential tremors **or** a disabling tremor causing limitations on ADL'S unresponsive to a 3-month trial of medication management**.**

SummaCare considers bilateral stimulation of the anterior nucleus of the thalamus medically necessary to treat adults ages 18 or older with partial onset seizures unresponsive to a 3-month trial to medical management.

Medicare Members

CMS NCD ID 160.24 Deep Brain Stimulation for Essential Tremor and Parkinson's Disease Indications and Limitations of Coverage

Effective for services furnished on or after April 1, 2003, 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:

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 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.

The 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.

Limitations

The following are unproven and not medically necessary due to insufficient evidence of efficacy:

- Deep brain stimulation and cortical stimulation for treating obsessive-compulsive disorder (OCD) and for all other indications not listed above.
- Responsive cortical stimulation for treating all other indications not listed above.

SummaCare considers deep brain stimulation (DBS) for tremors from other causes such as trauma, multiple sclerosis (MS), degenerative disorders, metabolic disorders, infectious diseases, and drug-induced movement disorders experimental and investigational.

SummaCare considers DBS experimental and investigational for the following indications (not an all-inclusive list), because there is insufficient evidence to support its effectiveness for these indications:

- Addiction
- Alzheimer's disease
- Anorexia nervosa
- Autism spectrum disorder
- Blepharospasm
- Cerebral palsy
- Chronic cluster headache
- Chronic pain syndrome including complex regional pain syndrome/reflex sympathetic dystrophy
- Chronic vegetative state
- Dementia
- Depression
- Disorders of consciousness (e.g., minimally conscious state, unresponsive wakefulness syndrome, and vegetative state) • Explosive aggressive behavior • Head or voice tremor
- Huntington's disease
- Obesity
- Obsessive-compulsive disorder
- Orthostatic tremor
- Parkinson’s disease-related camptocormia, dysarthria/speech deficits, postural instability, restless legs syndrome, and gait disorders (e.g., gait instability and freezing of gait) Posttraumatic tremor
- Parkinson’s stage V

- Postural trunk deformities
- Self-injurious behavior
- Substance use disorders
- Tinnitus
- Tourette syndrome
- Traumatic brain injury

CPT Codes

61850 Twist drill or burr hole(s) for implantation of neurostimulator electrodes, cortical

61860 Craniectomy or craniotomy for implantation of neurostimulator electrodes, cerebral, cortical

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 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 (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; first array

61868 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 with connection to 2 or more electrode arrays

61888 Revision or removal of cranial neurostimulator pulse generator or receiver

L8679 Implantable neurostimulator, pulse generator, any type

L8680 Implantable neurostimulator electrode, each

L8682 Implantable neurostimulator radiofrequency receiver

L8685 Implantable neurostimulator pulse generator, single array, rechargeable, includes extension

L8686 Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension

L8687 Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension

L8688 Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extensio

Coverage Decisions

Coverage decisions made per CMS Guidelines, Hayes Research and industry standards research

Plans Covered By This Policy

Commercial and Medicare
Self-funded Commercial groups refer to plan document for coverage

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