Medical Policy

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Medical policies in conjunction with other nationally recognized standards of care are used to make medical coverage decisions.

Title

Deep Brain Stimulation Policy

Title 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. (AANS, 2021)

Medical Indications for Authorization

Deep brain stimulation is medically necessary for treating the following conditions when criteria is met

- Dystonia
- Essential Tremor
- Parkinson's disease
- Refractory Epilepsy

Responsive cortical stimulation is proven and medically necessary for treating partial or focal seizure disorder. (UHC, 2021)

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. (UHC 2021), (Aetna 2021)

- Responsive cortical stimulation for treating all other indications not listed above. (UHC 2021)

SummaCare considers deep brain stimulation (DBS) for tremor from other causes such as trauma, multiple sclerosis (MS), degenerative disorders, metabolic disorders, infectious diseases, and drug-induced movement disorders experimental and investigational (Aetna 2021)

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 (Aetna 2021):

- 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
- 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)
- Post-traumatic tremor
- Postural trunk deformities
- Self-injurious behavior
- Substance use disorders
- Tinnitus
- Tourette syndrome
- Traumatic brain injury.

Research Summary

Medical and surgical interventions can provide benefit in up to 80% of patients with essential tremor. Deep brain stimulation is also an effective treatment for patients with advanced Parkinson's disease (PD) and motor complications that can no longer be improved by adjustment of medical therapy. The most common targets for implantation of deep brain stimulators are the subthalamic nucleus and globus pallidus internus (Aetna, 2021)

The American Academy of Neurology's practice parameter on the treatment of PD with motor fluctuations and dyskinesia (Pahwa et al, 2006) stated that pre-operative response to levodopa predicts better outcome after DBS of the subthalamic nucleus.

Deuschl and Bain (2002) noted that the appropriate selection of patients is essential for the outcome of surgical relief of tremors. The selection criteria should include: motor symptoms causing a relevant disability in activities of daily living, despite optimal pharmacotherapy; biological age of the patient; neurosurgical contraindications; and the patient is neither demented nor severely depressed.

Lyons and Pahwa (2008) stated that DBS has been used to treat various tremor disorders for several decades. Medication-resistant, disabling essential tremor is the most common tremor disorder treated with DBS. The treatment has been consistently reported to result in significant benefit in upper extremity, as well as head and voice tremor, all of which were improved more dramatically with bilateral procedures. These benefits have been demonstrated to be sustained for up to 7 years. Deep brain stimulation has also been shown to be beneficial for the tremor associated with multiple sclerosis and post-traumatic tremor; however, fewer cases have been reported and the benefit is less consistent, less dramatic, and more transient than that seen with essential tremor. The ventral

intermediate nucleus of the thalamus is the most common DBS target for tremor disorders, but more recent studies have demonstrated benefits in tremor from DBS of the subthalamic area, primarily the zona incerta. Surgical complications are relatively uncommon and are generally less frequent than those seen with thalamotomy. Stimulation-related effects are usually mild and resolve with adjustment of stimulation parameters. Deep brain stimulation is thus a relatively safe and effective treatment for tremor disorders, particularly for medication-resistant, disabling essential tremor, but may also have some role in medication-resistant, disabling tremor associated with multiple sclerosis and traumatic head injury. (Aetna, 2021)

On April 27, 2018, the FDA approved (via the PMA process) the Medtronic DBS System (bilateral stimulation of the anterior nucleus of the thalamus) as an adjunctive therapy for reducing the frequency of seizures in individuals 18 years of age or older diagnosed with epilepsy characterized by partial-onset seizures, with or without secondary generalization, that are refractory to 3 or more anti-epileptic medications. The Medtronic DBS System for Epilepsy has demonstrated safety and effectiveness in patients who averaged 6 or more seizures per month over the 3 most recent months prior to implant of the DBS system (with no more than 30 days between seizures). The Medtronic DBS System for Epilepsy has not been evaluated in patients with less frequent seizures (Voelker, 2018). Implantation of a DBS system is contraindicated for diathermy, MRI using a full body transmit radio-frequency (RF) coil, a receive-only head coil, or a head transmit coil that extends over the chest area, and transcranial magnetic stimulation. (Aetna 2021)

Klinger and Mittal (2018) noted that anti-epileptic drugs prevent morbidity and death in a large number of patients suffering from epilepsy. However, it is estimated that approximately 30% of epileptic patients will not have adequate seizure control with medication alone. Resection of epileptogenic cortex may be indicated in medically refractory cases with a discrete seizure focus in non-eloquent cortex. For patients in whom resection is not an option, DBS may be an effective means of seizure control. Deep brain stimulation targets for treating seizures primarily include the thalamic nuclei, hippocampus, sub-thalamic nucleus, and cerebellum. A variety of stimulation parameters have been studied, and more recent advances in electrical stimulation to treat epilepsy include responsive neuro-stimulation. The authors concluded that data suggested that DBS is effective for treating DRE. (Aetna, 2021)

The RNS System (NeuroPace, Inc. Mountain View, CA) is FDA approved by the premarket approval (PMA) application process. The device is indicated “as an adjunctive therapy in reducing the frequency of seizures in individuals 18 years of age or older with partial onset seizures who have undergone diagnostic testing that localized no more than two epileptogenic foci, are refractory to two or more antiepileptic medications, and currently have frequent and disabling seizures (motor partial seizures, complex partial seizures and/ or secondarily generalized seizures). The RNS System has demonstrated safety and effectiveness in patients who average three or more disabling seizures per month over the three most recent Page 21 of 42 Medical Coverage Policy: 0184 months (with no month with fewer than two seizures), and has not been evaluated in patients with less frequent seizures”. Exclusion criteria in the FDA clinical trial included subjects who did not have an implanted vagus nerve stimulator or an implanted device that delivers electrical energy to the head, had not had surgery for the treatment of epilepsy within the preceding six month, and had not been diagnosed with active psychosis, severe depression or suicidal ideation in the preceding year. If subject had a VNS, it must have been explanted (excluding leads) prior to or at the time of RNS implantation. VNS must have been discontinued for at least three months prior to enrollment (FDA, 2013),(Cigna 2021).

Continued approval of the PMA was contingent upon the submission of yearly reports including model number, number of devices sold and distributed. Also, NeuroPace must conduct and report on a long-term treatment study to establish safety (adverse event rates) and effectiveness (average disabling seizure frequency) through seven years. Successful responder rate is defined as sustained ≥ 50% reduction in total disabling seizures from baseline. Quality of life will also be measured.(Cigna 2021)

For use of deep brain stimulation (DBS) of the anterior nucleus of the thalamus (ANT) in adult patients diagnosed with epilepsy who have uncontrolled, partial-onset seizures (with or without secondary generalization) after ≥ 3 antiepileptic drugs. Hayes rating C. (Hayes, 2021)

Deep Brain Stimulation

Deep brain stimulation (DBS) is considered medically necessary for the treatment of ANY of the following:

- chronic, medically intractable primary dystonia (including generalized and/or segmental dystonia, hemidystonia, or cervical dystonia/torticollis) for an individual seven years of age or older when used in accordance with the Humanitarian Device Exemption (HDE) specifications of the U.S. Food and Drug Administration (FDA) chronic, medically intractable Parkinson disease (PD) when an FDA-approved device is used in accordance with the FDA-approved indications and an individual meets ALL of the following criteria:
- has intractable motor fluctuations or dyskinesia
- is levodopa-responsive
- does not have a significant mental impairment (e.g., dementia, severe depression) or a medical(e.g., stroke, cardiovascular disease) or surgical (e.g., previous ablative surgery such as thalamotomy, pallidotomy) contraindication to DBS
- chronic, medically intractable essential tremor (ET) when an FDA-approved device is used in accordance with the FDA-approved indications
- chronic, medically intractable epilepsy when an FDA-approved device is used in accordance with the FDA-approved indications and an individual meets ALL of the following criteria:
    - aged 18 years or older
    - has partial onset seizures with or without secondary generalization o has not responded to three or more antiepileptic medication

The replacement/revision of a deep brain stimulator or generator/battery and/or lead/electrode and/orpatient programmer is considered medically necessary for an individual who meets ALL of the above criteria and the existing generator/lead/programmer is no longer under warranty and cannot be repaired. (Cigna 2021)

Responsive Cortical Stimulation

Responsive cortical stimulation (e.g., NeuroPace® RNS® System) is considered medically necessary when ALL of the following criteria are met:

- age 18 years or older
- partial onset seizures
- seizures are refractory to two or more antiepileptic medications

- experiencing an average of three or more disabling seizures (e.g., motor partial seizures, complex partial and/or secondarily generalized seizures) per month over the three most recent months
- diagnostic testing confirms localized seizure onset to one or two foci
- not a candidate for focal resection epilepsy surgery
- not a candidate for vagus nerve stimulation

The replacement/revision of a responsive cortical stimulation neurostimulator/battery and/or leads and/or monitor is considered medically necessary for an individual who meets ALL of the above criteria and the existing neurostimulator/lead/monitor is no longer under warranty and cannot be repaired. (Cigna 2021)

Motor Cortex Stimulation

Motor cortex stimulation for any indication is considered experimental, investigational or unproven (Cigna 2021)

Coverage Decisions

CMS NCD Deep Brain Stimulation for Essential Tremor and Parkinson's Disease
Publication Number 100-3
Manual Section Number
160.24

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.

Plans Covered By This Policy

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

Sources Reviewed

https://www.aans.org/en/Patients/Neurosurgical-Conditions-and-Treatments/Deep-BrainStimulation

https://static.cigna.com/assets/chcp/pdf/coveragePolicies/medical/mm_0184_coveragepositioncriteria_deep_brain_stimulation_for_pd_and_et.pdf
https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-medicaldrug/deep-brain-cortical-stimulation.pdf

http://www.aetna.com/cpb/medical/data/200_299/0208.html

Hayes Knowledge Center | symplr (hayesinc.com)

https://www.cms.gov/medicare
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