



## Deep Brain Stimulation

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### Policy

The Medical Management Department reviews referral requests for authorization of deep brain stimulation.

This Medical Policy does not constitute medical advice. When deciding coverage, the enrollee's specific plan document must be referenced. The terms of an enrollee's plan document (Certificate of Coverage (COC) or Summary Plan Description (SPD)) may differ from this Medical Policy. In the event of a conflict, the enrollee's specific benefit plan document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements, and the plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. Quartz reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

### Procedure

#### **A. Documentation Required:**

To facilitate the authorization process referral requests must include **ALL** the following:

1. Documentation that a physician specializing in movement disorders or epilepsy as indicated is involved with selection of patients for deep brain stimulation treatment and post-procedure care.
2. Documentation of patient movement/neurologic symptoms, (e.g., tremor and degree of functional impairment and motor disability) using a tool to rate the level of disability, (e.g., Hoehn and Yahr stage, Unified Parkinson's disease rating scale (UPDRS) part 3 motor subscale or Fahn-Tolosa-Marin Clinical Tremor rating scale).
3. Documentation of seizure type and frequency, as indicated.
4. Documentation of failed treatments including medication trials and any adverse effects from medication trials.
5. Documentation of previous surgical procedures of the brain or implantation of nerve or brain stimulation devices.

#### **B. Criteria for Medical Necessity:**

1. **Refractory motor complication of Parkinson's disease:** The placement of an implantable Deep Brain Stimulation device (i.e., stimulation of the globus pallidus internus or the subthalamic nucleus) is considered medically necessary to treat patients with refractory motor complications of Parkinson's disease when **ALL** the following are met:
  - a. Persistent, disabling Parkinson's disease symptoms despite optimal medical therapy that includes  $\geq 12$  weeks of carbidopa-levodopa treatment and a 12-week trial of at least **ONE** of the following medications unless optimal medical therapy is not tolerated due to medication side effects:
    - i. Dopamine receptor agonist;
    - ii. Monamine oxidase B inhibitor;
    - iii. Catechol-o-methyltransferase (COMT) inhibitor;
    - iv. Anticholinergic;
    - v. Amantadine; **AND**

- b. Minimum score of 30 points on the UPDRS motor examination scale; **AND**
  - c. Responsive to levodopa therapy with clearly defined “on” periods (e.g., levodopa challenge response positive); **AND**
  - d. Does not have dementia, severe depression or Hoehn and Yahr stage V Parkinson’s disease (unable to get out of bed or chair without help); **AND**
  - e. Presence of at least 2 major symptoms of Parkinsonism (e.g., tremor, rigidity, and bradykinesia); **AND**
  - f. Device is FDA approved.
2. **Intractable limb tremors:** The placement of an implantable Deep Brain Stimulation device (i.e., stimulation of the globus pallidus internus, the subthalamic nucleus, or ventral intermediate thalamic nucleus) in patients with intractable tremors is considered medically necessary when **ALL** the following are met:
- a. Persistent tremor that leads to a significant disability in activities of daily living despite ≥ 12-week trial of optimal medical therapy that includes at least two medications (e.g., beta-blocker, antiepileptic or Botulinum toxin A) unless optimal medical therapy is not tolerated due to medication side effects; **AND**
  - b. Diagnosis of Essential Tremor or Parkinson’s disease as the cause of the tremor; **AND**
  - c. Alternative causes of tremor that could explain the failure to respond to therapy have been explored and do not exist; **AND**
  - d. Does not have dementia, severe depression or Hoehn and Yahr stage V Parkinson’s disease (unable to get out of bed or chair without help); **AND**
  - e. Device is FDA approved.
3. **Dystonia:** The placement of an implantable Deep Brain Stimulation device (i.e., stimulation of the globus pallidus internus or the subthalamic nucleus), in patients with dystonia is considered medically necessary when **ALL** the following are met:
- a. Age 7 or older; **AND**
  - b. Diagnosis of intractable **primary** dystonia, including generalized and/or segmental dystonia, hemidystonia and cervical dystonia; **AND**
  - c. Dystonia leads to a significant disability in activities of daily living despite optimal medical therapy that includes ≥ 12-week trial of at least one medication (e.g., trihexyphenidyl, benzodiazepine, tetrabenazine, baclofen) unless optimal medical therapy is not tolerated due to medication side effects; **AND**
  - d. Device is FDA approved for this condition and age.
4. **Intractable focal seizures:**
- A. The placement of a **responsive cortical stimulation/responsive neurostimulation (RNS) device (e.g., NeuroPace® RNS system)** in patients with seizure disorder is considered medical necessary when **ALL** the following are met:
- a. Age 18 years and older; **AND**
  - b. Diagnosis of focal seizures (i.e., complex partial seizures, motor partial seizures, or secondarily generalized seizures) that have undergone diagnostic testing and that localized no more than two epileptogenic foci, **AND**
  - c. Seizures are refractory to two or more antiepileptic medications, **AND**
  - d. Patient has frequent seizures with 3 or more disabling seizures per month over the past 3 months, **AND**
  - e. Patient has disabling seizures, (e.g., seizures impair functional ability or cause bodily injury); **AND**

- f. Patient is expected to have improved quality of life and decreased seizure frequency with use; **AND**
- g. Device is FDA approved.

**B. Deep brain stimulation of the anterior nucleus of thalamus** using an FDA approved device, e.g., Medtronic DBS for epilepsy in patients with seizure disorder is considered medically necessary when **ALL** the following are met:

- a. Age 18 years or older; **AND**
- b. Diagnosis of focal seizures (i.e., complex partial seizures, motor partial seizures, or secondarily generalized seizures) that have undergone diagnostic testing and that localized no more than two epileptogenic foci; **AND**
- c. Seizures are refractory to trials of 3 or more antiepileptic medications; **AND**
- d. Patient has frequent seizures with at least 6 per month over the past 3 months **AND**
- e. No more than 10 seizures per day on average, **AND**
- f. Patient does not have a progressive neurologic or medical disease causing the seizures ( e.g., brain tumor or neurodegenerative disease) **OR** a history of psychogenic seizures; **AND**
- g. Patient does not have a vagal nerve stimulator **OR** the device is planned to be removed at the time of the deep brain stimulator placement; **AND**
- h. The patient is able to operate the device or has a caregiver who can assist them with operating the device; **AND**
- i. Patient has been screened for depression and suicide risk and does not have severe depression or untreated depression; **AND**
- j. Patient is not pregnant.

**C. Indications Considered Experimental, Investigational or not Medically Necessary (Not an all-inclusive list):**

1. Deep brain stimulation for treatment of addiction or substance abuse disorders, autism, blepharospasm, cerebral palsy, chronic pain syndromes, coma, drug-induced movement disorders, head or voice tremor, Huntington’s disease, multiple sclerosis related movement disorders, post-traumatic tremor, secondary dystonia, traumatic brain injury, Tourette syndrome, vegetative state, or violent behavior.
2. First line treatment for Parkinson’s disease or Essential Tremor.
3. Movement disorder symptoms (e.g., tremor), that adequately respond to medication without significant adverse effects.
4. Patient has significant cognitive impairment, dementia, severe depression, or Hoehn and Yahr stage V Parkinson’s disease that could be worsened by or would interfere with the patient’s ability to benefit from deep brain stimulation.
5. Patients with prior movement disorder surgery within the affected basal ganglion.
6. Implantation of a non-FDA approved DBS device.

**CPT/ HCPCS 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	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
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
95971	simple spinal cord, or peripheral (i.e., peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
95974	complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
C1816	Receiver and/or transmitter, neurostimulator (implantable)
C1883	Adaptor/ extension, pacing lead or neurostimulator lead (implantable)
C1897	Lead, neurostimulator test kit (implantable)
E0745	Neuromuscular stimulator, electronic shock unit
L8680	Implantable neurostimulator electrode, each
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-hyphenrechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-hyphenrechargeable, includes extension

**References:**

American Academy of Neurology. Treatment of Essential Tremor. Published October 2011. Reaffirmed April 2014. Accessed February 18, 2019. Available at: <https://www.aan.com/Guidelines/home/GuidelineDetail/492>

Bergey G, Morrell M, Mizrahi E., et al. Long-term treatment with responsive brain stimulation in adults with refractory partial seizures. *Neurology*. 2015;84(8):810-817.

Bronte-Stewart H1, Taira T, Valldeoriola F, Merello M, Marks WJ Jr, Albanese A, Bressman S, Moro E. Inclusion and exclusion criteria for DBS in dystonia. *Mov Disord*. 2011 Jun;26 Suppl 1:S5-16. DOI: 10.1002/mds.23482. Accessed March 11, 2019.

Centers for Medicare and Medicaid Services. National Coverage determination for Deep Brain Stimulation for Essential Tremor and Parkinson’s Disease (160.24). Publication no. 100-3. Version no 1. Effective date 4/1/2003. Accessed February 18, 2019.

Fisher R, Salanova V, Witt T, et al. SANTE Study Group. Electrical stimulation of the anterior nucleus of thalamus for treatment of refractory epilepsy. *Epilepsia*. 2010;51:899–908.

Hayes, Inc. Search & Summary Report.

- Deep Brain Stimulation for Obsessive Compulsive Disorder. Published May 30, 2018. Accessed February 11, 2019.
- Deep Brain Stimulation of the anterior nucleus of the thalamus for treatment of refractory epilepsy. Published April 11, 2019. Accessed June 26, 2019.

Hayes, Inc. Vercise Deep Brain Stimulation (DBS) System (Boston Scientific) for Parkinson's Disease. Published January 22, 2019. Accessed February 11, 2019.

Li MCH, Cook MJ. Deep brain stimulation for drug-resistant epilepsy. *Epilepsia*. 2018;59(2):273-290. Accessed February 18, 2019.

Morrell MJ. Responsive cortical stimulation for treatment of medically intractable partial epilepsy. *Neurology*. 2011;77(13):1295-1304.

National Institute for Health and Care Excellence. Parkinson's disease in adults. NICE guideline. Published July 2017. Available at <https://www.nice.org.uk/guidance/NG71> Accessed February 18, 2019.

Rodrigues FB, Duarte GS, Prescott D, Ferreira J, Costa J. Deep brain stimulation for people with involuntary posturing, or dystonia. *Cochrane Database of Systematic Reviews* 2019, Issue 1. Art. No.: CD012405. DOI: 10.1002/14651858.CD012405.pub2. Accessed February 18, 2019.

Rughani A, Schwalb JM, Sidiropoulos C, et al. Congress of Neurological Surgeons systematic review and evidence-based guideline on subthalamic nucleus and globus pallidus internus deep brain stimulation for the treatment of patients with Parkinson's disease: executive summary. *Neurosurgery*. 2018;82(6):753-756. Accessed February 18, 2019.

Salanova V, Witt T, Worth R, et al. SANTE Study Group. Long-term efficacy and safety of thalamic stimulation for drug-resistant partial epilepsy. *Neurology*. 2015 Mar 10;84(10):1017-25.

Sprengers M, Vonck K, Carrette E, Marson AG, Boon P. Cochrane Epilepsy Group. Deep brain and cortical stimulation for epilepsy. *Cochrane Database of Systematic Reviews* 2017, Issue 7. Art. No.: CD008497. DOI: 10.1002/14651858.CD008497.pub3 Published July 18, 2017. Accessed February 11, 2019.

U.S. Food and Drug Administration. Premarket approval. Medtronic DBS Therapy for Epilepsy. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P960009S219> Accessed June 26, 2019.

U.S. Food and Drug Administration. Premarket approval. NeuroPace RNS System. Available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100026> Accessed March 8, 2019.

Zhou JJ, Chen T, Farber SH, Shetter AG, Ponce FA. Open-loop deep brain stimulation for the treatment of epilepsy: a systematic review of clinical outcomes over the past decade (2008-present). *Neurosurg Focus*. 2018;45(2): E5.