

Deep Brain Stimulation Clinical Coverage Criteria

Overview

Deep brain stimulation (DBS) consists of electrical stimulation of specific sites in the brain with implanted electrodes to reduce the symptoms of movement disorders such as Parkinson's disease and Essential Tremor. Targeted areas include the ventral intermediate nucleus of the thalamus, the internal globus pallidus and the subthalamic nucleus. Each of these brain regions has two halves which control movement on opposite sides of the body. Unilateral DBS has been proposed for use in patients when the symptoms are more severe on one side. Bilateral DBS has been proposed for the treatment of bilateral symptoms.

Policy

This Policy applies to the following Fallon Health products:

- □ Commercial

- NaviCare
- **⊠ PACE**

Fallon Health uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for Medicare Advantage, NaviCare and PACE plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare has a National Coverage Determination (NCD) for Deep Brain Stimulation for Essential Tremor and Parkinson's Disease (160.24). There are no LCDs or LCAs for deep brain stimulation.

Prior authorization is required.

Fallon Health follows Medicare NCD for Deep Brain Stimulation for Essential Tremor and Parkinson's Disease (160.24) indications and limitations of coverage for all plan members. Unilateral or bilateral thalamic ventralis intermedius nucleus (VIM) deep brain stimulation (DBS) is covered 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:

- The device is Food and Drug Administration (FDA) approved for DBS or used in accordance with FDA approved protocols governing Category B Investigational Device Exemption (IDE) DBS clinical trials.
- 2. For thalamic VIM DBS, members 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.

- 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, members 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 postsurgical evaluations, adjustments of medications and stimulator settings.

Exclusions

DBS is not reasonable and necessary and is not covered for ET or PD members with any of the following:

- Non-idiopathic Parkinson's disease or "Parkinson's Plus" syndromes.
- For other movement disorders, including but not limited to tardive dyskinesia multiple sclerosis, and post-traumatic dyskinesia chronic cluster headaches
- Cognitive impairment, dementia or depression, which would be worsened by or would interfere with the member's ability to benefit from DBS.
- Current psychosis, alcohol abuse or other drug abuse.
- Structural lesions such as basal ganglionic stroke, tumor or vascular malformation as etiology of the movement disorder.
- Previous movement disorder surgery within the affected basal ganglion.
- Significant medical, surgical, neurologic or orthopedic co-morbidities contraindicating DBS surgery or stimulation.
- For the treatment of other psychiatric or neurologic disorders, including but not limited to epilepsy, Tourette syndrome, depression, obsessive-compulsive disorder, anorexia nervosa, alcohol addiction, Alzheimer disease, and chronic pain.

Coding

Coding for deep brain stimulation consists of a series of CPT codes describing the various steps of the procedure, i.e., implantation of the electrodes, implantation of the pulse generator, intra-operative monitoring and programming of the electrodes, and postoperative neuro-programming. Patients may undergo several sessions of electronic analysis with or without programming to find the optimal programming parameters. For bilateral stimulation via implantation of two cranial neurostimulator pulse generators, each connected to a single lead, add modifier -50 to either 81885 or 61886. For bilateral stimulation via implantation of one cranial neurostimulator pulse generator, connected to two leads, use 61886.

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

Code	Description
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)
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
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
Revision or removal of intracranial neurostimulator electrodes
Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
Incision and subcutaneous placement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to two or more electrode arrays
Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse 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, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without programming
Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/ transmitter programming, first 15 minutes face-hyphento-hyphen face time with physician or other qualified health care professional
Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/ transmitter programming, each additional 15 minutes face-hyphento-hyphenface time with physician or other qualified health care professional (List separately in addition to code for primary procedure)l8680
Implantable neurostimulator pulse generator, any type
Implantable neurostimulator electrode, each
Patient programmer (external) for use with implantable programmable neurostimulator pulse generator
Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
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

References

- 1. Centers for Medicare & Medicaid Services (CMS) National Coverage Determination for Deep Brain Stimulation for Essential Tremor and Parkinson's Disease (160.24). Effective April 1, 2003. Available at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.
- 2. Mallet Luc, Polosan M, Jaafari N, et al. Subthalamic Nucleus Stimulation in Severe Obsessive-Compulsive Disorder. *N Engl J Med.* 2008;359(20):2121-34.
- 3. Ponce FA, Lozano AM. Deep brain stimulation state of the art and novel stimulation targets. Prog *Brain Res*.2010;184:311-24.
- 4. Williams A, Gill S, et al. Deep brain stimulation plus best medical therapy versus best medical therapy alone for advanced Parkinson's disease (PD SURG trial): a randomised, open-label trial. *Lancet Neurol.* 2010 June; 9(6): 581–591.
- 5. Jiménez MC, Vingerhoets FJ. Tremor revisited: treatment of PD tremor. *Parkinsonism Relat Disord.* 2012 Jan;18 Suppl 1:S93-5.
- 6. Bronte-Stewart H, Taira T, et al. Inclusion and exclusion criteria for DBS in dystonia. *Mov Disord.* 2011 Jun;26 Suppl. 1:S5-16.
- 7. Jahanshahi M, Czernecki V, Zurowski AM. Neuropsychological, neuropsychiatric, and quality of life issues in DBS for dystonia. *Mov Disord*. 2011 Jun;26 Suppl 1:S63-78.
- 8. Starr PA, Bejjani P, et al. Stereotactic techniques and perioperative management of DBS in dystonia. *Mov Disord*.2011 Jun;26 Suppl 1:S23-30.
- 9. Kahan J, Urner M, Moran R, et al, Resting state functional MRI in Parkinson's disease: the impact of deep brain stimulation on 'effective' connectivity. *Brain*. 2014 Apr;137(Pt 4):1130-44.
- 10. Liu Y, Li W, Tan C, Liu X, Wang X, Gui Y, Qin L, Deng F, Hu C, Chen L, Meta-analysis comparing deep brain stimulation of the globus pallidus and subthalamic nucleus to treat advanced Parkinson disease. *J Neurosurg.* 2014 Sep;121(3):709-18.
- 11. FitzGerald JJ, Rosendal F, de Pennington N, Joint C, Forrow B, Fletcher C, Green AL, Aziz TZ. Long-term outcome of deep brain stimulation in generalised dystonia: a series of 60 cases. *J Neurol Neurosurg Psychiatry*. 2014 Dec;85(12):1371-6.
- 12. Schlaepfer TE, Bewernick BH, et. al. Deep brain stimulation of the human reward system for major depression--rationale, outcomes and outlook. *Neuropsychopharmacology*. 2014 May;39(6):1303-14.
- 13. Eberhardt O, Reithmeier T, Topka H. [Long-term effects of deep brain stimulation for movement disorders: a literature-based analysis]. *Nervenarzt*. 2014 Dec;85(12):1551-60.
- 14. Fang JY, Tolleson C. The role of deep brain stimulation in Parkinson's disease: an overview and update on new developments. *Neuropsychiatr Dis Treat*. 2017 Mar 7;13:723-732.
- 15. Tsering D, Tochen L, Lavenstein B Considerations in deep brain stimulation (DBS) for pediatric secondary dystonia. *Childs Nerv Syst.* 2017 Feb 28.
- 16. Kohl S, Baldermann JC. Progress and challenges in deep brain stimulation for obsessive-compulsive disorder. *Pharmacol Ther.* 2018 Jan 31.

Policy history

Origination date: 11/01/2000

Approval(s): Benefits Committee: 01/2001

Technology Assessment Committee: 11/1/2000; 01/31/2006, 09/30/2009; 2/26/2014 ICD 10 CM codes mapped; 4/23/2014 correction due to ICD 10 CM implementation delay. 03/25/2015 (updated references) 03/23/2016 (removed ICD 9 codes, updated references) 04/26/2017 (updated references), 03/28/2018

(updated references), 03/27/2019 (removed termed codes, updated references), 05/27/2020 (updated criteria)

06/15/2021 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section).

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans. For Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this policy.