MEDICAL POLICY

Excellus

SUBJECT: DEEP BRAIN STIMULATION	EFFECTIVE DATE: 09/16/99 REVISED DATE: 07/19/01, 05/16/02, 03/20/03, 03/18/04, 03/17/05, 01/19/06, 01/18/07, 11/15/07, 11/20/08, 10/29/09, 10/28/10, 09/15/11, 08/16/12, 07/18/13, 06/19/14
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- ***If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.***
- ***Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.***
- ***Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.***

POLICY STATEMENT:

I. Based upon our criteria and assessment of the peer-reviewed literature, unilateral deep brain stimulation of the ventral intermediate nucleus (VIM) thalamus has been medically proven to be effective and therefore **medically appropriate** for disabling, medically unresponsive essential tremor or tremor due to Parkinson's disease.

Disabling, medically unresponsive tremor is defined as both of the following:
A. tremor causes significant limitation in daily activities; and
B. inadequate control by maximal dosage of medication for at least 3 months before implant.

II. Based upon our criteria and assessment of the peer-reviewed literature, bilateral deep brain stimulation of the subthalamic nucleus (STN) or of the globus pallidus interna (GPi) has been medically proven to be effective and therefore **medically appropriate** for treatment of advanced Parkinson's disease. All of the following criteria must be met:
A. the patient has a diagnosis of idiopathic (not secondary) Parkinson's disease;
B. the patient's Parkinson's disease was previously responsive to levodopa therapy but is now medically intractable; and
C. the patient has severe levodopa-induced dyskinesia or disease characterized by severe bradykinesia, rigidity, tremor or dystonia or by marked "on-off" fluctuations.

III. Based upon our criteria and assessment of peer-reviewed literature, unilateral or bilateral deep brain stimulation of the GPi or STN has been medically proven effective and therefore **medically appropriate** in patients 7 years of age or greater who experience chronic, intractable, primary dystonia, including generalized and focal dystonia.

IV. Based upon our criteria and assessment of the peer-reviewed literature, there is insufficient clinical evidence to support the safety and efficacy of deep brain stimulation, and is therefore considered **investigational** for the following conditions, including but not limited to:
A. Multiple Sclerosis,
B. post-traumatic dyskinesia;
C. all other movement disorders;
D. chronic pain syndromes, including cluster headache;
E. tardive dyskinesia;
F. epilepsy;
G. Tourette syndrome;
H. Dementias, including Alzheimer's disease;
I. Eating disorders, including Anorexia nervosa;
J. Alcohol addiction;
K. treatment-resistant depression; or
L. treatment-resistant obsessive compulsive disorder.

V. **Contraindications** to deep brain stimulation include:
A. patients who are not good surgical risks because of unstable medical problems;
B. patients who have a cardiac pacemaker;

C. patients who have medical conditions that require repeated MRI; or
D. patients who have neuropsychiatric disease that may interfere with their ability to benefit from deep brain stimulation.

Refer to Excellus Medical Policy #7.02.29 regarding Pallidotomy for Parkinson's Disease.

This medical policy does not address occipital nerve stimulation for chronic migraines or occipital neuralgia. In occipital nerve stimulation the neurostimulator delivers electrical impulses via insulated lead wires tunneled under the skin near the occipital nerves at the base of the head.

This medical policy does not address stimulation of the motor cortex, which has been investigated as a treatment for patients with chronic, refractory neuropathic pain and extremity weakness due to stroke. In motor cortex stimulation, electrodes are implanted subdurally over the sensorimotor cortex.

POLICY GUIDELINES:

I. Bilateral stimulators may be implanted simultaneously or in staged procedures.

II. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Deep brain stimulation (DBS) has been investigated as an alternative to permanent neuroablative procedures such as thalamotomy and pallidotomy. The procedure involves the stereotactic placement of an electrode into a targeted region of the brain. The electrode is then attached, via a cable/wire, to a programmable stimulator implanted subcutaneously. Deep brain stimulation is designed to turn off overactive brain regions without destroying them. The immediate advantage of DBS over conventional destructive surgery is that the lesions are titratable and hence reversible. After implantation, noninvasive programming of the neurostimulator can be adjusted to the patient's symptoms.

The effect of DBS depends on where the electrodes are placed. The 3 common target sites are the VIM thalamus, globulus pallidus interna and subthalamic nucleus. Whereas unilateral DBS of the thalamus is utilized to treat essential tremor or tremors of advanced Parkinson's disease, bilateral deep brain stimulation of the subthalamic nucleus (STN) or of the globus pallidus interna (GPi) is used for treatment of the entire constellation of Parkinsonian symptoms (e.g., tremor, rigidity, and bradykinesia).

DBS has also been investigated for the treatment of primary dystonia, defined as a neurological movement disorder characterized by involuntary and painful muscle contractions and contortions. Dystonia can be classified according to cause and the bodily distribution of symptoms. Primary or idiopathic dystonia is not associated with any other pathology whereas, secondary dystonia is caused by a known insult (e.g., trauma, infarct, stroke) to the basal ganglia. Generalized dystonia affects a wide range of body areas and focal dystonia affects specific body parts (e.g., spasmodic torticollis/ cervical dystonia, blepharospasm). Dystonia is the third most common movement disorder, behind Parkinson's disease and essential tremor. Unless contraindicated, DBS of either the GPi or STN requires a bilateral procedure.

In addition to essential tremors, Parkinson's disease, and dystonia, deep brain stimulation is also being investigated for disorders such as major depression, cluster headaches, chronic pain syndromes, Tourette syndrome, epilepsy and obsessive-compulsive disorder.

RATIONALE:

The Medtronic Activa Tremor Control system for unilateral deep brain stimulation of the thalamus was approved by the U.S. Food and Drug Administration (FDA) in 1997, and the supplemental pre-market application (PMA) for bilateral use of the device in the treatment of advanced Parkinson's disease was approved in January 2002. Deep brain stimulation is performed at specialty centers. In April of 2003, the FDA gave Humanitarian Device Exemption (HDE) approval to the Activa Therapy system for the unilateral or bilateral stimulation of the internal GPi or STN to aid in the management of

chronic, intractable (drug resistant) primary dystonia, including generalized and/or segmental dystonia, hemidystonia and cervical dystonia in patients seven years of age or greater.

Published clinical trials have provided evidence to support the efficacy and safety of unilateral deep brain stimulation of the VIM thalamus for essential tremor and for tremor of Parkinson's disease and of bilateral deep brain stimulation of the STN or GPi for advanced Parkinson's disease. In studies of unilateral thalamic DBS, tremor suppression was either total or clinically significant in 82-91% of patients who underwent implantation. Results were durable and side effects were minimal. An additional benefit of DBS is that recurrence of tremor may be managed by changes in stimulation parameters. Although long-term data are minimal, studies have demonstrated that bilateral stimulation of the GPi or STN results in improvements of neurologic function. Case series investigating the use of DBS for the treatment of dystonia found that patients with primary dystonia experienced significant improvement in movement and in ADL's, but those patients with secondary dystonia experienced little improvement.

The FDA approved Medtronic's *ReClaim* Deep Brain Stimulator device as the first implant to treat severe obsessive-compulsive disorder under a HDE approval in February 2009. The device is indicated for bilateral stimulation of the anterior limb of the internal capsule (AIC) as an adjunct to medications and as an alternative to anterior capsulotomy for the treatment of chronic, severe, treatment-resistant obsessive compulsive disorder in adult patients who have failed at least three selective serotonin reuptake inhibitors (SSRIs). The approval of the human device exemption was based on a review of data from 26 patients with severe treatment resistant OCD who were treated with the device at four sites. On average, patients had a 40 percent reduction in their symptoms after 12 months of therapy. One of the major limitations of this study was the fact that many of the study population were aware of when the device was turned on and off, so investigators were unable to rule out that some of the improvements were due to a placebo effect. While there is limited evidence to suggest that DBS may be an option for patients with severe, disabling OCD, well designed studies are necessary to demonstrate its long term safety and efficacy.

Published clinical trials have not provided evidence to support the efficacy and safety of deep brain stimulation for conditions including, but not limited to, Multiple Sclerosis, post-traumatic dyskinesia, treatment-resistant depression, Alzheimer's disease, Tourette syndrome, or for bilateral deep brain stimulation of the VIM thalamus. Studies of deep brain stimulation for the treatment of chronic pain have not provided evidence that this is an effective treatment method over already established treatment methods.

Results of Medtronic's SANTE trial (Fisher, et al. 2010) show promising outcomes on the adjunct use of deep brain stimulation of the anterior nucleus of the thalamus over placebo stimulation for patients suffering from severe, refractory, partial-onset seizures. Two years after implantation of the device, seizures were reduced by a median 56% compared with baseline and 14 patients (12.7%) became seizure-free for at least 6 months. The FDA has not yet granted FDA approval for the use of DBS in epilepsy and longer-term studies are needed to better define its safety, efficacy and the subset of patients who would benefit most from this treatment.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT:	61850	Twist drill or burr hole(s) for implantation of neurostimulator electrodes, cortical
	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	each additional array

	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	each additional array
	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 two or more electrode arrays
	61888	revision or removal of cranial neurostimulator pulse generator or receiver
	95970	electronic analysis of implanted neurostimulator pulse generator system; simple or complex brain, spinal cord, or peripheral neurostimulator pulse generator/transmitter, without programming
	95978	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, battery status, electrode selectability and polarity, impedance and patient compliance measurements) complex deep brain stimulator pulse generator/transmitter, with initial or subsequent programming, first hour
	95979	each additional 30 minutes after first hour

HCPCS:	L8679	Implantable neurostimulator pulse generator, any type
	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
	L8689	External recharging system for battery (internal) for use with implantable neurostimulator
ICD 9:	332.0	Paralysis agitans (Parkinson's disease)
	332.1	Secondary Parkinsonism
	333.1	Essential and other specified forms of tremor

	333.6	Idiopathic torsion dystonia
	333.7	Symptomatic torsion dystonia
	333.81	Blepharospasm
	333.83	Spasmodic torticollis
ICD 10:	G20	Parkinson's disease
	G21.11-G21.9	Parkinsonism (code range)
	G24.02-G24.3	Dystonia (code range)
	G24.5	Blepharospasm
	G24.8	Other dystonia
	G25.0	Essential tremor
	G25.1	Drug-induced tremor
	G25.2	Other specified forms of tremor
	G80.3	Athetoid cerebral palsy

REFERENCES:

*Abelson JL, et al. Deep brain stimulation for refractory obsessive-compulsive disorder. Biol Psych 2005 Mar 1;57(5):510-6.

Ackermans L, et al. Double-blind clinical trial of thalamic stimulation in patients with Tourette syndrome. Brain 2011 March;134(Pt 3):832-44.

Air EL, et al. Deep brain stimulation in children: experience and technical pearls. J Neurosurg Pediatr 2011 Dec;8(6):566-74.

American Psychiatric Association. Practice guideline for the treatment of patients with obsessive-compulsive disorder. [http://www.psychiatryonline.com/content.aspx?. aid=149171] accessed 5/9/14.

American Society of Stereotactic and Functional Neurosurgery. Deep brain stimulation: indications, techniques and practice parameters. 2010 [http://www.assfn.org/practice/dbs_statement.pdf] accessed 5/9/14.

*Anderson VC, et al. Pallidal vs subthalamic nucleus deep brain stimulation in Parkinson's disease. Arch Neurol 2005 Apr;62(4):554-60.

Andrade P, et al. A systematic review of the efficacy of globus pallidus stimulation in the treatment of Parkinson's disease. J Clin Neurosci 2009 Jul;16(7):877-81.

Andrade P, et al. Neurostimulatory and ablative treatment options in major depressive disorder: a systematic review. Acta Neurochir 2010 Apr;152(4):566-77.

Antonini A, et al. A 5-year prospective assessment of advanced Parkinson disease patients treated with subcutaneous apomorphine infusion or deep brain stimulation. J Neurol 2011 Apr;258(4):579-85.

*Appleby BS, et al. Psychiatric and neuropsychiatric adverse events associated with deep brain stimulation: A meta-analysis of ten years' experience. Mov Disord 2007 Sep 15;22(12):1722-8.

Baumer T, et al. Effects of DBS, premotor rTMS, and levodopa on motor function and silent period in advance Parkinson's disease. Mov Disord 2009 Apr 15;24(5):672-6.

Bewernick BH, et al. Nucleus accumbens deep brain stimulation decreases ratings of depression and anxiety in treatment-resistant depression. Biol Psychiatry 2010 Jan 15;67(2):110-6.

Blomstedt P, et al. Deep brain stimulation in the treatment of depression. Acta Psychiatr Scand 2011 Jan;123(1):4-11.

Blomstedt P, et al. Deep brain stimulation in the treatment of obsessive-compulsive disorder. World Neurosurg 2013 Dec;80(6):e245-53.

*BlueCross BlueShield Association Technology Evaluation Center (TEC). Bilateral DBS of the subthalamic nucleus or the globus pallidus interna for treatment of advanced Parkinson's disease. 2002 Feb.

BlueCross BlueShield Association. Deep brain stimulation. Medical Policy Reference Manual Policy #7.01.63. 2013 Jun 13.

Boccard SG, et al. Long-term outcomes of deep brain stimulation for neuropathic pain. Neurosurgery 2013 Feb;72(2):221-30.

Borggraefe I, et al. Bilateral pallidal stimulation in children and adolescents with primary generalized dystonia- report of six patients and literature-based analysis of predictive outcomes variables. Brain Dev 2010 Mar;32(3):223-8.

Bronstein JM, et al. Deep brain stimulation for Parkinson disease: an expert consensus and review of key issues. Arch Neurol 2011 Feb;68(2):165-71.

Cannon E, et al. Deep brain stimulation of anteromedial globus pallidus interna for severe Tourette's syndrome. Am J Psychiatry 2012 Aug 1;169(8):860-6.

*Capecci M, et al. Functional improvement after subthalmic stimulation in Parkinson's disease: a non-equivalent controlled study with 12-24 month follow up. J Neurol Neurosurg Psych 2005 Jun;76(6):769-74.

Castrioto A, et al. Ten-year outcome of subthalamic stimulation in Parkinson disease: a blinded evaluation. Arch Neurol 2011 Dec;68(12):1550-6.

*Charles PD, et al. Is deep brain stimulation neuroprotective if applied early in the course of PD? Nat Clin Pract Neurol 2008 Aug;4(8):424-6.

Clarke CE, et al. Systematic review of apmorphine, levodopa infusion and deep brain stimulation in advanced Parkinson's disease. Parkinsonism Relat Disord 2009 Dec;15(10):728-41.

*Coubes, P, et al. Treatment of DYT11-generalized dystonia by stimulation of the internal globus pallidus. Lancet 2000;355:2220-1.

*Coubes P, et al. Electrical stimulation of the globus pallidus internus in patients with primary generalized dystonia: long-term results. J Neurosurg 2004 Aug;101(2):189-94.

*Damier P, et al. Bilateral deep brain stimulation of the globus pallidus to treat tardive dyskinesia. Arch Gen Psych 2007 Feb;64(2):170-6.

*Deuschl G, et al. A randomized trial of deep-brain stimulation for Parkinson's disease. NEJM 2006 Aug 31;355(9):896-908.

Denys D, et al. Deep brain stimulation of the nucleus accumbens for treatment-refractory obsessive-compulsive disorder. Arch Gen Psychiatry 2010 Oct;67(10):1061-8.

deSouza RM, et al. Timing of deep brain stimulation in Parkinson disease: a need for reappraisal? Ann Neurol 2013 May;73(5):565-75.

*Diamond A, et al. Globus pallidus deep brain stimulation in dystonia. Mov Disord 2006 May;21(5):692-5.

*Egidi M, et al. A survey of Italian cases of dystonia treated by deep brain stimulation. J Neurosurg Sci 2007 Dec;51(4):153-8.

*Eltahawy HA, et al. Primary dystonia is more responsive than secondary dystonia to pallidal interventions: outcomes after pallidotomy or pallidal deep brain stimulation. Neurosurg 2004 Mar;54(3):613-21.

*Esselink RA, et al. Unilateral pallidotomy versus bilateral subthalamic nucleus stimulation in PD: a randomized trial. Neurol 2004 Jan 27;62(2):201-7.

Esselink RA, et al. Long-term superiority of subthalamic nucleus stimulation over pallidotomy in Parkinson disease. Neurology 2009 Jul 14;73(2):151-3.

*Figueiras-Mendez R, et al. Further supporting evidence of beneficial subthalamic stimulation in Parkinson's patients. Neurol 2002 Feb12;58(3):469-70.

Fisher R, et al. Electrical stimulation of the anterior nucleus of the thalamus for treatment of refractory epilepsy. Epilepsia 2010 May 5;51(5):899-908.

Flora ED, et al. Deep brain stimulation for essential tremor: a systematic review. Mov Disord 2010 Aug 15;25(11):1550-9.

Fontaine D, et al. Safety and efficacy of deep brain stimulation in refractory cluster headache: a randomized placebo-controlled double-blind trial followed by a 1-year open extension. J Headache Pain 2010 Feb;11(1):23-31.

Fontaine D, et al. Anatomical location of effective deep brain stimulation electrodes in chronic cluster headache. Brain 2010 Apr;133(pt 4):1214-33.

*Ford B, et al. Subthalmic nucleus stimulation in advanced Parkinson's disease: blinded assessments at one year follow up. J Neurol Neurosurg Psych 2004 Sep;75(9):1255-9.

*Fraix V, et al. Clinical and economic results of bilateral subthalamic nucleus stimulation in Parkinson's disease. J Neurol Neurosurg Psych 2006 Apr;77(4):443-9.

*Franzini A, et al. Stimulation of the posterior hypothalamus for treatment of chronic intractable cluster headaches: first reported series. Neurosurg 2003 May;52(5):1095-9.

Franzini A, et al. Deep-brain stimulation for aggressive and disruptive behavior. World Neurosurg 2013 Sep-Oct;80(3-4):S29.e11-14.

*Germano IM, et al. Unilateral stimulation of the subthalmic nucleus in Parkinson disease: a double-blind 12-month evaluation study. J Neurosurg 2004 Jul;101(1):36-42.

Gervais-Bernard H, et al. Bilateral subthalamic nucleus stimulation in advanced Parkinson's disease: five year follow-up. J Neurol 2009 Feb;256(2):225-33.

Gimeno H, et al. Improvement in upper limb function in children with dystonia following deep brain stimulation. Eur J Paediatr Neurol 2013 Jul;17(4):353-60.

Goodman WK, et al. Deep brain stimulation for intractable obsessive compulsive disorder: pilot study using a blinded, staggered-onset design. Biol Psychiatry 2010 Mar 15;67(6):535-42.

Grabli D, et al. Interruption of deep brain stimulation of the globus pallidus in primary generalized dystonia. Mov Disord 2009 Dec 15;24(16):2363-9.

*Greenberg BD, et al. Three-year outcomes in deep brain stimulation for highly resistant obsessive-compulsive disorder. Neuropsychopharmacol 2006 Nov;31(11):2384-93.

*Greenberg BD, et al. Deep brain stimulation of the ventral internal capsule/ventral striatum for obsessive-compulsive disorder: worldwide experience. Mol Psychiatry 2008 May 20 [Epub ahead of print].

Grover PJ, et al. Deep brain stimulation for cluster headache. J Clin Neurosci 2009 Jul;16(7):861-6.

Gruber D, et al. Long-term effects of pallidal deep brain stimulation in tardive dystonia. Neurol 2009 Jul 7;73(1):53-8.

*Halbig TD, et al. Pallidal stimulation in dystonia: effects on cognition, mood, and quality of life. J Neurol Neurosurg Psych 2005 Dec;76(12):1713-6.

Harries AM, et al. Deep brain stimulation of the subthalamic nucleus for advanced Parkinson disease using general anesthesia: long-term results. J Neurosurg 2012 Jan;116(1):107-13.

*Hauptman JS, et al. Potential surgical targets for deep brain stimulation in treatment-resistant depression. Neurosurg Focus 2008;25(1):E3.

Haynes WI, et al. High-frequency stimulation of deep brain structures in obsessive-compulsive disorder: the search for a valid circuit. Eur J Neurosci 2010 Oct;32(7):1118-27.

Hescham S, et al. Deep brain stimulation in dementia-related disorders. Neurosci Biobehav Rev 2013 Dec;37(10 Pt 2):2666-75.

Holtzheimer PE, et al. Subcallosal cingulate deep brain stimulation for treatment-resistant unipolar and bipolar depression. Arch Gen Psychiatry 2012 Feb;69(2):150-8.

*Hung SW, et al. Long-term outcome of bilateral pallidal deep brain stimulation for primary cervical dystonia. Neurol 2007 Feb 6;68(6):457-9.

*Institute for Clinical Systems Improvement (ICSI). Technology Assessment Report. Deep brain stimulation for essential tremor and Parkinson's disease. Updated Apr 2005. [http://icis.org/knowlwdge/detail.asp?catID=306& itemID=276] accessed 5/13/14.

Johnsen EL, et al. Improved symmetry of gait in Parkinson's disease with DBS: gait and postural instability in Parkinson's disease treated with bilateral deep brain stimulation in the subthalmic nucleus. Mov Disord 2009 Mar 15;24(4):590-697.

Kahn E, et al. Deep brain stimulation in early stage Parkinson's disease: operative experience from a prospective randomized clinical trial. J Neurol Neurosurg Psychiatry 2012 Feb;83(2):164-70.

Kennedy SH, et al. Canadian Network for Mood and Anxiety Treatments (CANMAT) Clinical guidelines for the management of major depressive disorder in adults. IV. Neurostimulation therapies. J Affect Disord 2009 Oct;117(Suppl 1):S44-53.

Kennedy SH, et al. Deep brain stimulation for treatment-resistant depression: follow-up after 3 to 6 years. Am J Psychiatry 2011 May;168(5):502-10.

Kim HJ, et al. Two-year follow-up on the effect of unilateral subthalmic deep brain stimulation in highly asymmetric Parkinson's disease. Mov Disord 2009 Feb 15;24(3):329-35.

*Kiss ZH, et al. The Canadian multicentre study of deep brain stimulation for cervical dystonia. Brain 2007 Nov;130(Pt11):2879-86.

*Kleiner-Fisman G, et al. Subthalamic nucleus deep brain stimulation: summary and meta-analysis of outcomes. Mov Disord 2006 Jun;21(Suppl 14):S290-304.

Koy A, et al. Effects of deep brain stimulation in dyskinetic cerebral palsy: a meta-analysis. Mov Disord 2013 May;28(5):747-54.

*Krause M, et al. Deep brain stimulation for the treatment of Parkinson's disease: subthalamic nucleus versus globus pallidus internus. J Neurol Neurosurg Psych 2001 Apr;70(4):464-70.

*Krauss JK, et al. Pallidal deep brain stimulation in patients with cervical dystonia and severe cervical dyskinesias with cervical myelopathy. J Neurol Neurosurg Psych 2002 Feb;72(2):249-56.

*Kupsch A, et al. Pallidal deep-brain stimulation in primary generalized or segmental dystonia. NGJM 2006 Nov 9;355(19):1978-90.

Laxton AW, et al. A phase I trial of deep brain stimulation of memory circuits in Alzheimer's disease. Ann Neurol 2010 Oct;68(4):521-534.

Laxton AW, et al. Deep brain stimulation for the treatment of Alzheimer disease and dementia. World Neurosurg 2013 Sep-Oct;80(3-4):S28.e1-8.

*Lee JY, et al. Thalmic deep brain stimulation for management of essential tremor. J Neurosurg 2005 Sep;103(3):400-3.

*Leone M, et al. Lessons from 8 years' experience of hypothalamic stimulation in cluster headache. Cephalalgia 2008 Jul;28(7):787-97.

Levy R, et al. Intracranial neurostimulation for pain control: a review. Pain Physician 2010 Mar;13(2):157-65.

Lipsman N, et al. Subcallosal cingulate deep brain stimulation for treatment-refractory anorexia nervosa: a phase 1 pilot study. Lancet 2013 Apr 20;381(9875):1361-70.

*Liu W, et al. Quantitative assessments of the effect of bilateral subthalamic stimulation on multiple aspects of sensorimotor function for patients with Parkinson's disease. Parkinsonism Relat Disord 2005 Dec;11(8):503-8.

*Loher TJ, et al. Long-term follow-up study of chronic globus pallidus internus stimulation for post-traumatic hemidystonia. J Neurosurg 2000 Mar;92(3):457-60.

*Loher TJ, et al. Long-term pallidal deep brain stimulation in patients with advanced Parkinson disease: 1-year follow-up study. J Neurosurg 2002 May;96(5):844-53.

Lozano AM, et al. A multicenter pilot study of subcallosal cingulate area deep brain stimulation for treatment-resistant depression. J Neurosurg 2012 Feb;116(2):315-22.

*Ludwig J, et al. Effects of subthalamic nucleus stimulation and levodopa on the autonomic nervous system in Parkinson's disease. J Neurol Neurosurg Psych 2007 Jul;78(7):742-5.

*Mallet L, et al. Subthalmic nucleus stimulation in severe obsessive-compulsive disorder. NEJM 2008 Nov 13;359(20):2121-34.

*Mayberg H, et al. Deep brain stimulation for treatment-resistant depression. Neuron 2005 Mar 3;45: 651-60.

Mehrkens JH, et al. Long-term efficacy and safety of chronic globus pallidus internus stimulation in different types of primary dystonia. Stereotact Funct Neurosurg 2009;87(1):8-17.

Mentzel CL, et al. Efficacy and safety of deep brain stimulation in patients with medication-induced tardive dyskinesia and/or dystonia: a systematic review. J Clin Psychiatry 2012 Nov;73(11):1434-8.

Merola A, et al. Subthalamic nucleus deep brain stimulation outcome in young onset Parkinson's disease: a role for age at disease onset? J Neurol Neurosurg Psychiatry 2012 Mar;83(3):251-7.

Moro E, et al. Pallidal stimulation in cervical dystonia: clinical implications of acute changes in stimulation parameters. Eur J Neurol 2009 Apr;16(4):506-12.

Moro E, et al. Long-term results of a multicenter study on subthalamic and pallidal stimulation in Parkinson's disease. Mov Disord 2010 Apr 15;25(5):578-86.

*Mueller J, et al. Pallidal deep brain stimulation improves quality of life in segmental and generalized dystonia: results from a prospective, randomized sham-controlled trial. Mov Disord 2008 Jan;23(1):131-4.

*Nakamura K, et al. Effects of unilateral subthalamic and pallidal deep brain stimulation on fine motor functions in Parkinson's disease. Mov Disord 2007 Apr 15;22(5):619-26.

*National Institute for Health and Clinical Excellence. Deep brain stimulation for tremor and dystonia (excluding Parkinson's disease). 2006 Aug [http://www.nice.org.uk/topic] accessed 5/9/14.

*National Institute for Health and Clinical Excellence. Deep brain stimulation for Parkinson's disease. 2003 Nov [http://www.nice.org.uk/topic] accessed 5/9/14.

National Institute for Health and Clinical Excellence. Deep brain stimulation for intractable trigeminal automatic cephalalgias. 2011 Mar [http://www.nice.org.uk/topic] accessed 5/9/14.

National Institute for Health and Clinical Excellence. Deep brain stimulation for refractory chronic pain syndromes. 2011 Mar [http://www.nice.org.uk/topic] accessed 5/9/14.

National Institute for Health and Clinical Excellence. Deep brain stimulation for refractory epilepsy. 2012 Jan [http://www.nice.org.uk/topic] accessed 5/9/14.

*Obwegeser AA, et al. Quantitative and qualitative outcome measures after thalamic deep brain stimulation to treat disabling tremors. Neurosurg 2001 Feb;48(2):274-84.

Odekerken VJ, et al. Subthalamic nucleus versus globus pallidus bilateral deep brain stimulation for advanced Parkinson's disease (NSTAPS): a randomized controlled trial. Lancet Neurol 2013 Jan;12(1):37-44.

Okun MS, et al. Cognition and mood in Parkinson's disease in subthalmic nucleus versus globus pallidus interna deep brain stimulation: the COMPARE trial. Ann Neurol 2009 May;65(5):586-95.

Okun MS, et al. Subthalamic deep brain stimulation with a constant-current device in Parkinson's disease: an open-label randomized controlled trial. Lancet Neurol 2012 Feb;11(2):140-9.

*Ondo W, et al. Thalamic deep brain stimulation: comparison between unilateral and bilateral placement. Arch Neurol 2001 Feb;58(2):218-22.

Ooms P, et al. Deep brain stimulation for obsessive-compulsive disorders: long-term analysis of quality of life. J Neurol Neurosurg Psychiatry 2014 Feb;85(2):153-8.

Ostrem JL, et al. Subthalamic nucleus deep brain stimulation in primary cervical dystonia. Neurol 2011 Mar 8;76(10):870-8.

*Owen SL, et al. Deep brain stimulation for the alleviation of post-stroke neuropathic pain. Pain 2006 Jan;120(1-2):202-6.

*Pahwa R, et al. Long-term evaluation of deep brain stimulation of the thalamus. J Neurosurg 2006 Apr;104 (4):506-12.

*Pahwa R, et al. 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. Neurol 2006 Apr 11;66(7):983-95.

Pansaon Piedad JC, et al. What patients with gilles de la Tourette syndrome should be treated with deep brain stimulation and what is the best target? Neurosurg 2012 Jul;71(1):173-92.

Panov F, et al. Deep brain stimulation in DYT1 dystonia: a 10-year experience. Neurosurgery 2013 Jul;73(1):86-93.

Pereira EA, et al. Thalmic deep brain stimulation for neuropathic pain after amputation or brachial plexus avulsion. Neurosurg Focus 2013 Sep;35(3):E7.

Petrossian MT, et al. Pallidal deep brain stimulation for dystonia: a case series. J Neurosurg Pediatr 2013 Dec;12(6);582-7.

*Piboolnurak P, et al. Levodopa response in long-term bilateral subthalamic stimulation for Parkinson's disease. Mov Disord 2007 May 15;22(7):990-7.

*Pretto TE, et al. A prospective blinded evaluation of deep brain stimulation for the treatment of secondary dystonia and primary torticollis syndromes. J Neurosurg 2008 Sep;109(3):405-9.

*Rasche D, et al. Deep brain stimulation for the treatment of various chronic pain syndromes. Neurosurg Focus 2006 Dec 15;21(6):E8.

*Rodriguez-Oroz MC, et al. Efficacy of deep brain stimulation of the subthalamic nucleus in Parkinson's disease 4 years after surgery: double blind and open label evaluation. J Neurol Neurosurg Psych 2004 Oct;75(10):1382-5.

*Rodriquez-Oroz MC, et al. Bilateral deep brain stimulation in Parkinson's disease: a multicentre study with 4 years follow-up. Brain 2005 Oct;128(pt 10):2240-9.

*Rodrigues JP, et al. Globus pallidus stimulation in advanced Parkinson's disease. J Clin Neurosci 2007 Mar;14(3):208-15.

Roh D, et al. Long-term follow-up of deep brain stimulation for refractory obsessive-compulsive disorder. Psychiatry Res 2012 Dec 30;200(2-3):1067-70.

*Schlaepfer TE, et al. Deep brain stimulation for treatment of refractory depression. Lancet 2005 Oct 22-28;366(9495):1420-2.

Schjerling L, et al. A randomized double-blind crossover trial comparing subthalamic and pallidal deep brain stimulation for dystonia. J Neurosurg 2013 Dec;119(6):1537-45.

*Schupbach WM, et al. Neurosurgery at an earlier stage of Parkinson disease: a randomized, controlled trial. Neurol 2007 Jan 23;68(4):267-71.

*Schuurman PR, et al. A comparison of continuous thalamic stimulation and thalamotomy for suppression of severe tremor. NEJM 2000 Feb 17;342(7):505-8.

Sensi M, et al. Pallidal stimulation for segmental dystonia: long-term follow up of 11 consecutive patients. Mov Disord 2009 Sep 15;24(12):1829-35.

Sharma A, et al. Efficacy and safety of deep brain stimulation as an adjunct to pharmacotherapy for the treatment of Parkinson disease. Ann Pharmacother 2012 Feb;46(2):248-54.

*Skogseid IM. Pallidal deep brain stimulation is effective, and improves quality of life in primary segmental and generalized dystonia. Acta Neurol Scand Suppl 2008;188:51-5.

*Slowinski JL, et al. Unilateral deep brain stimulation of the subthalamic nucleus for Parkinson disease. J Neurosurg 2007 Apr;106(4):626-32.

Steeves T, et al. Canadian guidelines for the evidence-based treatment of tic disorders: behavioral therapy, deep brain stimulation, and transcranial magnetic stimulation. Can J Psychiatry 2012 Mar;57(3):144-51.

Taghva AS, et al. Deep brain stimulation for treatment-resistant depression. World Neurosurg 2013 Sep-Oct;80(3-4):S27.e17-24.

*Temel Y, et al. Single electrode and multiple electrode guided electrical stimulation of the subthalamic nucleus in advanced Parkinson's disease. Neurosurg 2007 Nov;61(5 Suppl 2):346-55.

*Tir M, et al. Exhaustive, one-year follow-up of subthalamic nucleus deep brain stimulation in a large, single-center cohort of Parkinsonian patients. Neurosurg 2007 Aug;61(2):297-304.

*The Deep Brain Stimulation for Parkinson's Disease Study Group. Deep-brain stimulation of the subthalamic nucleus or the pars interna of the globus pallidus in Parkinson's disease. NEJM 2001 Sep;345(35):956-63.

Valentin A, et al. Deep brain stimulation of the centromedian thalamic nucleus for the treatment of generalized and frontal epilepsies. Epilepsia 2013 Oct;54(10):1823-33.

Valldeoriola F, et al. Efficacy and safety of pallidal stimulation in primary dystonia: results of the Spanish multicentric study. J Neurol Neurosurg Psych 2010 Jan;81(1):65-9.

*Vidailhet M, et al. Bilateral deep-brain stimulation of the globus pallidus in primary generalized dystonia. NEJM 2005 Feb 3;352(5):459-67.

*Vidailhet M, et al. Bilateral, pallidal, deep-brain stimulation in primary generalized dystonia: a prospective 3 year follow-up study. Lancet Neurol 2007 Mar;6(3):201-2.

*Visser-Vanderwalle V, et al. Long-term effects of bilateral subthalmic nucleus stimulation in advanced Parkinson disease: a four year follow-up study. Parkinsonism Relat Disord 2005 May;113(3):157-65.

Voges J, et al. Deep brain stimulation surgery for alcohol addiction. World Neurosurg 2013 Sep-Oct:80(3-4):S28.e21-31.

Volkmann J, et al. Pallidal deep brain stimulation in patients with primary generalized or segmental dystonia: a 5-year follow-up of a randomized trial. Lancet Neurol 2012 Dec;11(12):1029-38.

Vonck K, et al. A decade of experience with deep brain stimulation for patients with refractory medial temporal lobe epilepsy. Int J Neural Syst 2013 Feb;23(1):1250034.

Walsh RA, et al. Bilateral pallidal stimulation in cervical dystonia: blinded evidence of benefit beyond 5 years. Brain 2013 Mar;136(Pt3):761-9.

Weaver FM, et al. Bilateral deep brain stimulation vs best medical therapy for patients with advanced Parkinson disease: a randomized trial. JAMA 2009 Jan 7;301(1):63-73.

*Welter ML, et al. Internal pallidal and thalamic stimulation in patients with Tourette's syndrome. Arch Neurol 2008 Jul;65(7):952-7.

Williams A, et al. Deep brain stimulation plus best medical therapy versus best medical therapy alone for advanced Parkinson's disease (PD SURG trial): a randomized, open-label trial. Lancet Neurol 2010 Jun;9(6):581-91.

Wu H, et al. Deep-brain stimulation for anorexia nervosa. World Neurosurg 2013 Sep-Oct:80(3-4):S29.e1-10.

*Zesiewicz TA, et al. Practice parameter: therapies for essential tremor: report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurol 2005 Jun 28;64(12):2008-20.

Zesiewicz TA, et al. Evidence-based guideline update: treatment of essential tremor: report of the Quality Standards subcommittee of the American Academy of neurology. Neurology 2011 Nov 8;77(19):1752-5.

*Zorzi G, et al. Stimulation of the globus pallidus internus for childhood-onset dystonia. Mov Disord 2005 Sep;20(9):1194-200.

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KEY WORDS:

Brain stimulation, Parkinson's disease, Reclaim, Thalamus, Tremor, dystonia.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NC)) for deep brain stimulation. Please refer to the following NCD website for Medicare Members: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=279&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&CptHcpcsCode=36514&bc=gAAAABAAAAAA&.