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Subject: Deep Brain Stimulation and Responsive Neurostimulation

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Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

DESCRIPTION:

Deep brain stimulation (DBS) involves the stereotactic placement of an electrode into a central nervous system nucleus (eg, hypothalamus, thalamus, globus pallidus, subthalamic nucleus). Deep brain stimulation is used as alternative to permanent neuroablative procedures for control of essential tremor and Parkinson disease. Deep brain stimulation is also being evaluated for the treatment of a variety of other neurologic and psychiatric disorders. Since 1997 the U.S. Food and Drug Administration (FDA) has approved several DBS systems.

Responsive neurostimulation (RNS) for the treatment of epilepsy involves the use of one or more implantable electric leads that serve both a seizure detection and neurostimulation function. The device is programmed using a proprietary algorithm to recognize seizure patterns from electrocorticography output and to deliver electrical stimulation with the goal of terminating a seizure. One device, the NeuroPace RNS® System, has FDA approval for the treatment of refractory focal (formerly partial) epilepsy.

RNS shares some features with DBS, but is differentiated by its use of direct cortical stimulation and by its use in both monitoring and stimulation. The RNS system provides stimulation in response to detection of specific epileptiform patterns, while DBS provides continuous or intermittent stimulation at preprogrammed settings.

Summary and Analysis of Evidence: The evidence for treatment of essential tremor or tremor in Parkinson disease with deep brain stimulation (DBS) of the thalamus includes a systematic review and case series. The systematic review concluded that there was sufficient evidence that DBS of the thalamus results in clinically significant tremor suppression and that outcomes after DBS were at least as good as thalamotomy. Subsequent studies reporting long-term follow-up have supported the

conclusions of the systematic review and found that tremors were effectively controlled 5 to 6 years after DBS. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. Symptoms (eg, speech, motor fluctuations) associated with Parkinson disease treated with DBS of the globus pallidus interna or subthalamic nucleus, the evidence includes randomized controlled trials (RCTs) and systematic reviews. One review concluded that studies evaluating DBS of the globus pallidus interna or subthalamic nucleus have consistently demonstrated clinically significant improvements in outcomes (eg, neurologic function). Other systematic reviews have also found significantly better outcomes after deep DBS than after a control intervention. An RCT in patients with levodopa-responsive Parkinson disease of at least 4 years in duration and uncontrolled motor symptoms found that quality of life at 2 years was significantly higher when DBS was provided in addition to medical therapy. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. DBS of the globus pallidus interna or subthalamic nucleus for the treatment of primary dystonia, the evidence includes systematic reviews, RCTs, and case series. A pooled analysis of 24 studies, mainly uncontrolled, found improvements in motor scores and disability scores after 6 months and at last follow-up (mean, 32 months). Both double-blind RCTs found that severity scores improved more after active than after sham stimulation. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. DBS for treatment of epilepsy, the evidence includes systematic reviews, RCTs, and many observational studies. The observational studies reported fewer seizures compared with baseline, however, without control groups, interpretation of these results is limited. Additional trials are required to determine the impact of DBS on patient outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Treatment of cluster headaches or facial pain with DBS, the evidence includes a systematic review, randomized crossover study, and case series. The systematic review included an individual patient data meta-analysis of 34 patients, showing a significant reduction in pain intensity at 3 months following DBS for chronic facial pain; data for follow-up beyond 3 months were not eligible for statistical analysis. In an RCT of 11 patients with severe, refractory, chronic cluster headache , the between-group difference in response rates did not differ significantly between active and sham stimulation phases. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. An UpToDate review titled, Deep brain Stimulation for Treatment of Obsessive-Compulsive Disorder (2025) includes, “The efficacy of DBS for OCD [obsessive-compulsive disorder] has not been established, but preliminary trials, either uncontrolled or inadequately controlled, have shown promising results. Of 63 patients with treatment-refractory OCD who have received DBS, 34 experienced a reduction of symptoms of 35 percent or more. DBS is an experimental procedure that has been used to treat incapacitating and treatment-refractory OCD. Given the invasive nature of DBS and the relative lack of efficacy data, we suggest that patients with OCD only be treated with DBS in the context of a clinical trial.” The evidence for OCD treated with DBS includes RCTs, several systematic reviews and meta-analyses. Many of the studies had limited sample sizes. Studies suggest there may be improvements in OCD symptoms after DBS treatment, but have also identified a substantial number of adverse events and the optimal target(s) has not been determined. Additional blinded controlled studies are needed to draw conclusions about the impact of DBS on the net health benefit. Tourette syndrome treated with DBS, the evidence includes observational studies, RCTs, and systematic reviews. Two RCTs with 15 or more patients have been reported. One RCT found differences in severity of Tourette syndrome for active versus sham at 3 months while the other RCT did not. Neither study demonstrated improvements in comorbid symptoms of OCD or depression. Both

studies reported high rates of serious adverse events. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. DBS for the treatment of tardive dyskinesia or tardive dystonia, the evidence includes an RCT and case series. Additional studies, especially RCTs or other controlled studies, are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Treatment-resistant depression treatment with DBS, the evidence includes RCTs, systematic reviews, prospective controlled trials, and case series. A controlled crossover trial randomized patients to sham or active stimulation of the anterior limb of the internal capsule after a year of open-label stimulation. DBS for patients with major depressive disorder who have failed all other treatment options is an active area of research, but the brain regions that might prove to be effective for treatment-resistant depression have yet to be established. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Treatment of other neurologic or psychiatric disorders with DBS, the evidence includes a number of nonrandomized studies or RCTs in patients with multiple sclerosis, chronic pain, or alcohol use disorder. One RCT with 10 multiple sclerosis patients, 2 RCTs in patients with chronic pain, and 1 RCT in patients with treatment-refractory alcohol use disorder is insufficient evidence on which to draw conclusions about the efficacy of DBS in these populations. Additional trials are required. Patients with anorexia nervosa, Alzheimer disease, Huntington disease, or chronic pain who receive DBS, the evidence includes case series; RCTs are needed to evaluate the efficacy of DBS for these conditions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Refractory focal epilepsy treated with responsive neurostimulation, the evidence includes an industry-sponsored randomized controlled trial, which was used for FDA approval of the NeuroPace RNS System, as well as several published follow-up analyses. The randomized controlled trial reported that responsive neurostimulation is associated with improvements in mean seizure frequency in patients with refractory focal epilepsy, with an absolute difference in change in seizure frequency of about 20% between groups; however, the percentage of treatment responders with at least a 50% reduction in seizures did not differ from sham control. The number of adverse events reported in the available studies is low. Patients who are candidates for responsive neurostimulation are in general severely debilitated and have few other treatment options, so the benefits are likely high relative to the risks. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

POSITION STATEMENT:

Deep Brain Stimulation

Unilateral deep brain stimulation of the thalamus **meets the definition of medical necessity** when used in the treatment of members with disabling, medically unresponsive tremor due to essential tremor or Parkinson disease.

Bilateral deep brain stimulation of the thalamus **meets the definition of medical necessity** in members with disabling, medically unresponsive tremor in both limbs due to essential tremor or Parkinson disease.

Unilateral or bilateral deep brain stimulation of the globus pallidus or subthalamic nucleus **meets the definition of medical necessity** for the following members:

- Members with Parkinson disease and **ALL** of the following:

- A good response to levodopa; **AND**
- Motor complications not controlled by pharmacologic therapy; **AND**
- **ONE** of the following:
    a. A minimum score of 30 points on the motor portion of the Unified Parkinson Disease Rating Scale (UPDRS) when the member has been without medication for approximately 12 hours; **OR**
    b. Parkinson disease for at least 4 years.

- Members seven (7) years of age or above with chronic, intractable (drug refractory) primary dystonia, including generalized or segmental dystonia, hemidystonia and cervical dystonia (torticollis).

NOTE: Pulse generator replacement can be expected and may be necessary 3 – 5 years following the initial placement, when the initial procedure was a covered service.

Deep brain stimulation for other movement disorders, including but not limited to tardive dyskinesia and post-traumatic dyskinesia is considered **experimental or investigational**. The evidence is insufficient to determine the effects of the technology on health outcomes.

Deep brain stimulation for the treatment of chronic cluster headaches is considered **experimental or investigational**. The evidence is insufficient to determine the effects of the technology on health outcomes.

Deep brain stimulation is considered **experimental or investigational** for the treatment of other psychiatric or neurologic disorders, including but not limited to Tourette syndrome, depression, obsessive-compulsive disorder, Alzheimer disease, anorexia nervosa, alcohol addiction, multiple sclerosis tremor, chronic pain, and epilepsy. The evidence is insufficient to determine the effects of the technology on health outcomes.

Responsive Neurostimulation

Responsive neurostimulation **meets the definition of medical necessity** for members with focal epilepsy who meet **ALL** of the following criteria:

- Are 18 years or older;
- Have a diagnosis of focal seizures with 1 or 2 well-localized seizure foci identified;
- Have an average of 3 or more disabling seizures (eg, motor focal seizures, complex focal seizures, or secondary generalized seizures) per month over the prior 3 months;
- Are refractory to medical therapy (have failed 2 or more appropriate antiepileptic medications at therapeutic doses);
- Are not candidates for focal resective epilepsy surgery (eg, have an epileptic focus near the eloquent cerebral cortex; have bilateral temporal epilepsy); **AND**
- Do not have contraindications for RNS device placement (contradictions include 3 or more specific seizure foci, presence of primary generalized epilepsy, or presence of a rapidly progressive neurologic disorder).

Responsive neurostimulation is considered **experimental or investigational** for all other indications. The evidence is insufficient to determine the effects of the technology on health outcomes.

Revision/Replacement

Revision or replacement of an implanted neurostimulator **meets the definition of medical necessity** when all of the criteria above for deep brain stimulation or responsive neurostimulation are met, the device is not functioning, and is no longer under warranty or cannot be repaired.

BILLING/CODING INFORMATION:

CPT Coding:

61850	Twist drill or burr hole for implantation of neurostimulator electrode, 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	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; 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	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; each additional array (list separately in addition to primary procedure)
61880	Revision or removal of intracranial neurostimulator
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays
61888	Revision or removal of cranial neurostimulator pulse generator or receiver
61889	Insertion of skull-mounted cranial neurostimulator pulse generator or receiver, including craniectomy or craniotomy, when performed, with direct or inductive coupling, with connection to depth and/or cortical strip electrode array(s)
61891	Revision or replacement of skull-mounted cranial neurostimulator pulse generator or receiver with connection to depth and/or cortical strip electrode array(s)
61892	Removal of skull-mounted cranial neurostimulator pulse generator or receiver with cranioplasty, when performed

95970	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 careprofessional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter,without programming
95971	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 simple spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95983	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-to-face time with physician or other qualified health care professional
95984	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-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure)

HCPCS Coding:

L8679	Implantable neurostimulator pulse generator, any type
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-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

ICD-10 Diagnosis Codes That Support Medical Necessity:

G20.A1- G20.C	Parkinson's disease
G21.0 – G21.9	Secondary Parkinsonism
G24.01 - G24.9	Dystonia
G25.0	Essential tremor
G40.001	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, with status epilepticus
G40.009	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, not intractable, without status epilepticus
G40.011	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, with status epilepticus
G40.019	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, without status epilepticus
G40.101	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, with status epilepticus
G40.109	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, without status epilepticus
G40.111	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, with status epilepticus
G40.119	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, without status epilepticus
G40.201	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, with status epilepticus
G40.209	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, without status epilepticus
G40.211	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, with status epilepticus
G40.219	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, without status epilepticus
G40.C01-G40.C19	Lafora progressive myoclonus epilepsy

LOINC Codes:

The following information may be required documentation to support medical necessity: Physician history and physical, attending physician progress notes that include documentation of symptoms, behavior or pharmacologic interventions, plan of treatment, and laboratory studies.

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Attending physician progress notes	18741-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Plan of treatment	18776-5	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Laboratory studies	26436-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim

REIMBURSEMENT INFORMATION:

Refer to sections entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage Products:

The following National Coverage Determinations (NCDs) located at www.cms.gov were reviewed on the last guideline reviewed date:

- Electrical Nerve Stimulators (160.7)
- Deep Brain Stimulation for Essential Tremor and Parkinson's Disease (160.24).

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request

DEFINITIONS:

Disabling, medically unresponsive tremor: tremor causes significant limitation in daily activities and inadequate control by maximal dosage of medication for at least 3 months before implant.

Unified Parkinson Disease Rating Scale (UPDRS): an overall assessment rating tool used to follow the longitudinal course of Parkinson's disease (PD). It is made up of several sections including: evaluation of mentation, behavior,mood, activities of daily living, and motor examination. UPDRS is used to follow the progression of a person's Parkinson's disease.

RELATED GUIDELINES:

Vagus Nerve Stimulation, 02-61000-22

OTHER:

None Applicable

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 06/26/25.

GUIDELINE UPDATE INFORMATION:

04/15/02	1. Changed Medical Coverage Guideline name from Deep Brain Stimulation of the Thalamus for Tremor to Deep Brain Stimulation (DBS).Revised description section of MCG to include 2002 FDA expanded information for Medtronic's Activa Tremor Control System.Revised coverage criteria to expand coverage statement for Parkinson's disease.Deleted CPT coding that may be used to report DBS.Added definition for Unified Parkinson Disease Rating Scale (UPDRS).Updated references.
11/15/03	Review. References updated. Revised Coverage Criteria to mirror new FDA indication.
10/15/04	Review and revision; consisting of addition of CPT codes 61863 – 61868, 61880 – 61888; addition of HCPCS codes E0752 and E0756; addition of definition for dyskinesia; and updated references.
01/01/05	Annual HCPCS update: consisting of addition of 95978, 95979 and revision of 61885, 61886.
10/15/05	Review and revision of guideline; consisting of updated references.
01/01/06	Annual HCPCS update: consisting of the deletion of E0752 and E0756 and the addition of L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688 and L8689.
10/15/06	Review and revision of guideline consisting of updated references.
01/01/07	Annual HCPCS coding update: consisting of the revision of L8689 and the addition of L8695.
07/15/07	Review; coverage statements maintained; Medicare Advantage section updated; guideline reformatted; references updated.
10/15/08	Review and revision of guideline consisting of updated references.
01/01/09	Annual HCPCS coding update: revised descriptor for codes L8681, L8689, and L8695.
08/15/09	Annual Review: position statement maintained, and updated the description section and references.
01/01/10	Annual HCPCS coding update: revised descriptor for code 61886.
06/15/10	Annual review: position statements maintained and references updated.
10/15/10	Revision; related ICD-10 codes added.
05/15/11	Annual review; position statements maintained, formatting changes, references updated.
10/01/11	Revision; formatting changes.
05/15/12	Annual review; position statements maintained, coding information, program exception, and references updated; formatting changes.
05/15/13	Annual review; position statements maintained, program exception and references updated.
01/01/14	Annual HCPCS update. Added code L8679.
02/15/15	Annual review; Title, DBS position statements, coding, & references updated; RNS position statements added; formatting changes.
10/01/15	Revision; ICD9 & ICD10 coding section updated.
11/01/15	Revision: ICD-9 Codes deleted.

10/01/16	Revision; formatting changes.
06/15/17	Revision; position statement and references updated.
06/15/18	Revision; description, position statements, and references updated.
01/01/19	Annual CPT/HCPCS coding update. Added codes 95983, 95984, revised codes 95970, 95971; deleted codes 95978, 95979.
06/15/19	Review; position statements maintained and references updated.
08/15/21	Review; Description, position statements, coding, and references updated.
12/15/22	Review: position statements maintained; references updated.
05/25/23	Update to Program Exceptions section.
10/01/23	Annual ICD10 coding update. Codes G20.A1-G20.C added; code G20 deleted.
01/01/24	Position statements maintained. Annual CPT/HCPCS coding update. Codes 61889-61892 added.
07/15/24	Review: Revision/replacement position statement added; description and references updated.
07/15/25	Review: Position statements maintained and references updated.