02-61000-24

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Subject: Deep Brain Stimulation and Responsive Neurostimulation

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Deep brain stimulation (DBS) involves the stereotactic placement of an electrode into the brain (i.e., hypothalamus, thalamus, globus pallidus, or subthalamic nucleus). The electrode is initially attached to a temporary transcutaneous cable for short-term stimulation to validate treatment effectiveness. Several days later, the patient returns for permanent subcutaneous implantation of the cable and a radiofrequency-coupled or battery-powered programmable stimulator. After implantation, noninvasive programming of the neurostimulator can be adjusted to the patient's symptoms. 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 as 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.

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's disease (PD).

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's 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 minimal 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 is considered **experimental or investigational for all other indications**, including but not limited to the following:

- Multiple sclerosis
- Post-traumatic dyskinesia
- Tardive dyskinesia
- Degenerative disorders
- Chronic cluster headaches
- Drug induced movement disorders.

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, 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 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.

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
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
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only
L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only

ICD-10 Diagnosis Codes That Support Medical Necessity:

G20	Parkinson's disease
G21.11 – G21.9	Secondary Parkinsonism
G24.09 – G24.3 G24.8, 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

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).

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:

Occipital Nerve Stimulation, 02-61000-06
Sacral Nerve Neuromodulation/Stimulation, 02-61000-23
Spinal Cord and Dorsal Root Ganglion Stimulation, 02-61000-05

OTHER:

None Applicable

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 05/23/19.

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.