Deep Brain Stimulation and Cortical Stimulation

INDEPENDENT CARE HEALTH PLAN

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Medicare Advantage Medical Coverage Policy

Table of Contents

Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to CMS website for the most current applicable CMS Online Manual System (IOMs)/National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/ Transmittals.

Type	Title	ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories

Internet Only Manuals	Medicare Benefit Policy Manual Chapter 15 – Covered Medical and Other Health Service	§120 - Prosthetic Devices		
NCD	Deep Brain Stimulation for Essential Tremor and Parkinson's Disease	160.24		
NCD	Electrical Nerve Stimulators	160.7		
NCD	Treatment of Motor Function Disorders with Electric Nerve Stimulation	160.2		
LCD LCA	Category III Codes	L35490 A56902	J5 – J8 - Wisconsin Physicians Service Insurance Corporation	IA, KS, MO, NE IN, MI
LCD LCA	Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS) for Tremor	L37421 A57435	J6 – JK - National Government Services, Inc. (Part A/B MAC)	IL, MN, WI CT, NY, ME, MA, NH, RI, VT
LCD LCA	Magnetic Resonance Guided Focused Ultrasound Surgery System (MRgFUS) for the treatment of neurologic conditions	L37790 A58323	J15 - CGS Administrators, LLC (Part A/B MAC)	KY, OH
LCD LCA	Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor and Tremor Dominant Parkinson's Disease	L37729 A57512	JE - Noridian Healthcare Solutions, LLC	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands
LCD LCA	Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor and Tremor Dominant Parkinson's Disease	L37738 A57513	JF - Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
LCD LCA	Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor	L38495 A57839	JH – JL Novitas Solutions, Inc. (Part A/B MAC)	AR, CO, NM, OK, TX, LA, MS DE, D.C., MD, NJ, PA
LCD LCA	Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS) for Essential Tremor	L37761 A56690	JJ – JM - Palmetto GBA (Part A/B MAC)	AL, GA, TN NC, SC, VA, WV
LCD LCA	Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor	L38506 A57884	JN - First Coast Service Options, Inc. (Part A/B MAC)	FL, PR, U.S. VI

Description

Deep brain stimulation (DBS) involves the surgical placement of electrodes, also called leads, in selected areas of the brain to treat neurological disorders. The electrodes are placed using magnetic resonance imaging (MRI) or computed tomography (CT) to guide the neurosurgeon to the site to be stimulated.

Fiducial markers are small titanium screws, which may be placed into the anesthetized scalp prior to DBS, to assist physicians with stereotactic or computerized targeting for the exact DBS lead location during surgery. After placement, a CT scan is performed to verify accuracy. The fiducial markers remain in place until after DBS leads are inserted.

During DBS lead placement, the individual may be asked to move their fingers or toes or answer questions. This stimulation test helps the surgeon confirm accurate placement and effectiveness of the permanent electrodes in the brain. These are later connected to a neurostimulator (also referred to as a neurotransmitter or pulse generator) that is implanted under the skin, usually near the collarbone. The battery operated neurostimulator sends high frequency electrical signals to the electrodes which inhibit the activity in that region of the brain. The DBS is programmed with the intensity, frequency and duration according to the individual's symptoms and can be readjusted as symptoms change.

Directional deep brain stimulation enables the current to be steered precisely to the targeted structural area avoiding areas of stimulation that could cause side effects.

Examples of US Food & Drug Administration (FDA) approved DBS devices include, but may not be limited to:

- Activa RC neurostimulator for essential tremor (ET) and Parkinson's disease [59]
- Activa SC neurostimulator for chronic, intractable primary dystonia including generalized and/or segmental dystonia, hemidystonia and cervical dystonia (torticollis)[65]
- Infinity DBS system for ET and Parkinson's disease[27]
- Reclaim DBS for obsessive compulsive disorder (OCD)[66]
- SenSight directional lead system (SenSight lead, Percept PC stimulator) for dystonia, epilepsy, ET and Parkinson's disease
- Vercise directional system (Cartesia lead, and DBS, Genus, Gevia or PC stimulators) for ET and Parkinson's disease[64]

Stimulation of the anterior nucleus of the thalamus reduces the frequency of seizures in adults with drug resistant or medically refractory epilepsy providing neuromodulation therapy to change how brain cells work by delivering electrical stimulation to the areas involved in seizures. This stimulation is performed

bilaterally. An example of an FDA-approved DBS device for the treatment of drug-resistant epilepsy is the Medtronic DBS System for Epilepsy.[34,62]

Cortical stimulation is a treatment option for individuals with refractory focal epilepsy and a well delineated seizure focus which may be useful when resective epilepsy surgery is not possible. Cortical stimulation devices use a closed-loop cortical stimulation unit paired to a seizure detection system.[24,34,48] An example of an FDA-approved cortical stimulation system is the NeuroPace RNS System which is used as an adjunct to medication in adults with partial onset seizures from no more than two foci that are refractory to two or more antiepileptic medications. The device is implanted in the skull while the individual is under general anesthesia. [28,33,63]

The implantable components include a neurostimulator, a depth lead and a cortical strip lead. The external components include the programmer, a laptop computer with proprietary software that has a wand and telemetry interface enabling communication with an implanted RNS neurostimulator. Physicians use the programmer to noninvasively program the detection and stimulation parameters of an implanted device and are able to view the individual's brain electrical activity in real time as well as upload information that has been stored in the RNS neurostimulator.

The system monitors brain activity to detect seizures as they start and delivers electrical stimulation to the seizure focus to stop seizure activity before it becomes clinically apparent. The typical individual is treated with a cumulative total of 5 minutes of stimulation a day and the treatment is reversible.

Magnetic resonance guided focused ultrasound (MRgFUS, [eg, ExAblate Neuro]), is a treatment option that purportedly treats medication refractory ET or movement disorder and tremor dominant Parkinson's disease. MRgFUS therapy, also called transcranial MR-guided high-intensity focused ultrasound (MRgHIFU), uses a stereotactic head frame/helmet like device with a cooling cap and an individual ultrasound transducer to thermally ablate the thalamus in the ventral intermediate nucleus creating an intracranial therapeutic lesion. The MR images assist in treatment positioning providing real time feedback. The created lesion disrupts the brain activity thought to be responsible for an ET. This procedure is performed unilaterally and is less invasive than DBS implantation or a traditional thalamotomy that involves drilling or boring a hole into the skull to create a therapeutic lesion.

Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

Please refer to the above CMS guidance for **Deep brain stimulation**.

Please refer to the above CMS guidance for **MRgFUS/MRgHIFU.**

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the criteria contained in the following:

Cortical Stimulation

Cortical stimulation (eg, NeuroPace RNS) will be considered medically reasonable and necessary **ALL** of the following criteria are met[28,33,63]:

- Partial-onset seizures; **AND**
- Currently averaging 3 or more disabling seizures (eg, partial motor seizures, complex partial seizures and/or secondarily generalized seizures) a month over the 3 most recent months; **AND**
- Individual is able to or has the necessary assistance to properly operate the device or magnet; **AND**
- Individual is not pregnant; **AND**
- No more than 2 epileptogenic foci localized by diagnostic testing; **AND**
- Refractory to 2 or more antiepileptic medications; **AND**
- No other implanted medical devices that deliver electrical energy to the brain; **AND**
- Not currently a candidate for resective epilepsy surgery; **AND**
- Not high risk for surgical complications such as active systemic infection, coagulation disorders (such as the use of antithrombotic therapies) or platelet count below 50,000; **AND**
- The device is FDA approved

Replacement/revision of a stimulator/generator/battery and/or lead/electrode and/or programmer is considered medically necessary if the original generator/lead/programmer is no longer under warranty and cannot be repaired.[10]

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

DBS will not be considered medically reasonable and necessary for any indications other than those listed above including, but not limited to the following[11,22,30,37]:

- Alzheimer's Disease[21]
- Cerebral palsy[43]

- Chronic neuropathic pain[42]
- Cluster headaches[45]
- Depression[8, 27, 57, 58]
- Movement disorder caused by multiple sclerosis (MS)[52]
- Obsessive compulsive disorder (OCD)[7,9,23,35,46]
- Orthostatic tremor
- Tourette syndrome[4,54]

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment for these indications. There remains an absence of randomized blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management for these indications.

The placement of fiducial markers is considered integral to the primary procedure and not separately reimbursable.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
61850	Twist drill or burr hole(s) for implantation of neurostimulator electrodes, 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 (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)	
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	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 (List separately in addition to primary procedure)	
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	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	
64999	Unlisted procedure, nervous system	

95961	Functional cortical and subcortical mapping by stimulation and/or recording of electrodes on brain surface, or of depth electrodes, to provoke seizures or identify vital brain structures; initial hour of attendance by a physician or other qualified health care professional	
95962	Functional cortical and subcortical mapping by stimulation and/or recording of electrodes on brain surface, or of depth electrodes, to provoke seizures or identify vital brain structures; each additional hour of attendance by a physician or other qualified health care professional (List separately in addition to code for primary procedure)	
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 care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming	
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)	

CPT® Category III Code(s)	Description	Comments
0398T	Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed	
HCPCS Code(s)	**Description**	**Comments**
C1767	Generator, neurostimulator (implantable), nonrechargeable	
C1778	Lead, neurostimulator (implantable)	
C1787	Patient programmer, neurostimulator	
C1816	Receiver and/or transmitter, neurostimulator (implantable)	
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system	
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system	
C1826	Generator, neurostimulator (implantable), includes closed feedback loop leads and all implantable components, with rechargeable battery and charging system	
C1827	Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller	
C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)	
C1897	Lead, neurostimulator test kit (implantable)	
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, nonrechargeable, includes extension	
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension	
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension	
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only	

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Change Summary

- 01/01/2024 New Policy.
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