Regence

Medicare Advantage Policy Manual **Policy ID:** M-SUR84

Deep Brain Stimulation (DBS)

Published: 07/01/2025

Next Review: 03/2026

Last Review: 05/2025 ***Medicare Link(s) Revised:*** *07/01/2025*

IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

"Deep brain stimulation (DBS) refers to high-frequency electrical stimulation of anatomic regions deep within the brain utilizing neurosurgically implanted electrodes. These DBS electrodes are stereotactically placed within targeted nuclei on one (unilateral) or both (bilateral) sides of the brain. There are currently three targets for DBS -- the thalamic ventralis intermedius nucleus (VIM), subthalamic nucleus (STN) and globus pallidus interna (GPi)."[1]

MEDICARE ADVANTAGE POLICY CRITERIA

Note: This policy only applies to ***deep brain stimulation*** (DBS). For ***responsive neurostimulation*** (RNS) using technology such as the NeuroPace RNS® System, see *Cross References* below.

CMS Coverage Manuals*	For ***removal only of an DBS device,*** as well as ***revision/replacement*** of *not medically necessary devices*: Medicare Benefit Policy Manual Chapter 16 - General Exclusions From Coverage *See Section 180 in the following link:* §180 - Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare Note: Please read the applicable section, in its entirety, for complete criteria details. ***Removal only*** (without replacement) of a device may be allowed as medically necessary when the removal is required in order to treat a medical condition or complication. Even if initial placement of the device did not meet medical necessity coverage criteria and the complication or subsequent medical condition is the result of a prior non-covered service, coverage may be allowed in select circumstances for the removal of the device. However, a procedure or device that doesn't meet medical necessity criteria is non-covered and any ***revision or replacement*** to allow for the *continued* use of the non-covered device would not be expected to meet Medicare's general requirements for coverage. For ***revision/replacement*** requests of previously placed *medically necessary devices*: Medicare Benefit Policy Manual Chapter 15 – Covered Medical and Other Health Services *See Section 120 in the following link:* §120 - Prosthetic Devices, D. Supplies, Repairs, Adjustments, and Replacement[1] Note: Replacement of previously placed medically necessary devices or their components that are non-functioning and irreparable (e.g., device malfunction, etc.) may be considered medically necessary in accordance with the above Medicare reference if the stimulator continues to be medically indicated and is no longer under manufacturer warranty or if the component is not included under the warranty.[1]
National Coverage Determinations (NCDs)*	For initial placement of DBS for the treatment of ***chronic intractable pain***:

	✓ Electrical Nerve Stimulators (160.7) For initial placement of DBS for the treatment of ***essential tremor (ET) and Parkinson's disease***: ✓ Deep Brain Stimulation for Essential Tremor and Parkinson's Disease (160.24) *(Medicare will cover [1] unilateral or bilateral thalamic VIM DBS as a treatment of ET and/or Parkinsonian tremor or [2] unilateral or bilateral STN or GPi DBS as a treatment of PD only under conditions outlined in this NCD.)* For initial placement of DBS for the treatment of ***all other motor function disorders (e.g., including but not limited to, multiple sclerosis, cerebral Palsy, Tourette syndrome, etc.)***: ✓ Treatment of Motor Function Disorders with Electric Nerve Stimulation (160.2)
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*	None
Medical Policy Manual	*Medicare coverage guidance is not available for deep brain stimulation (DBS) for some indications. Therefore, the health plan's medical policy is applicable for any indication not addressed by a Medicare policy.* For initial placement of DBS for ***any indication NOT addressed above (e.g., including but not limited to, anxiety, bipolar disorder, etc.)***: ✓ Deep Brain Stimulation, Surgery, Policy No. 84 *(see "NOTE" below)*

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (*Medicare IOM Pub. No. 100-04, Ch. 23, §30 A*). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an ***objective, evidence-based process, based on authoritative evidence***. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

For initial placement:

- Condition intended to be treated (Parkinson's disease, essential tremor, a motor function disorder such as multiple sclerosis, intractable pain, etc.);
- Bilateral or unilateral stimulation;
- targeted nuclei
    - thalamic ventralis intermedius nucleus (VIM)
    - subthalamic nucleus (STN) or
    - globus pallidus interna (GPi);
- Name of device (only FDA-approved devices ***or*** devices used within the context of a Category B IDE clinical trial will be considered for coverage);
- If chronic intractable pain is the condition being treated, include the following:
    - Documentation of other treatments that have attempted and failed or determined to be unsuitable or contraindicated for the individual patient (implantation of the stimulator should be used only as a last resort);
    - Medical records with history, physical, evaluation and screening (physical and psychological) prior to implantation; and,
    - Demonstrated pain relief with temporarily implanted electrode should proceed permanent implantation.
- Any other documentation requested to support medical necessity criteria are met.

For replacement:

- For replacement of irreparable devices or their components, documentation must support reason for replacement (e.g., device malfunction, etc.) and whether or not the stimulator is still under manufacturer warranty.

For revisions and removal only (without replacement):

- Revisions to previously placed medically necessary devices and removals do not require additional documentation.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) has approved a number of deep brain stimulation systems for the treatment of essential tremor and tremor due to PD that is not adequately controlled by medication and is causing significant disability. The following DBS devices have been FDA-approved to treat essential tremor and PD-associated tremors under the Premarket Approval Application (PMA) process:

- Master Percept, Percept PC, And Activa® Deep Brain Stimulation Therapy Systems, with SenSight™ DBS accessories, Medtronic, Inc.
- Brio Neurostimulation System, Abbott St. Jude Medical Infinity™ Deep Brain Stimulation (DBS) system, Abbott (formerly St. Jude Medical).
- Vercise Deep Brain Stimulation System, including Vercise™ PC, Vercise Gevia™, and Vercise Genus™, Boston Scientific

The FDA has approved DBS systems for other indications. The Medtronic DBS System for Epilepsy (Medtronic, Inc) was FDA-approved through the PMA process as an adjunctive therapy for reducing the frequency of seizures in individuals 18 years of age or older diagnosed with epilepsy characterized by partial-onset seizures, with or without secondary generalization, that are refractory to three or more antiepileptic medications.

The Reclaim device (Medtronic, Inc.) was FDA-approved via the Humanitarian Device Exemption (HDE) process for the treatment of severe obsessive-compulsive disorder (OCD).

CROSS REFERENCES

Transcranial Magnetic Stimulation as a Treatment of Depression and Other Disorders, Medicine, Policy No. M-148

Investigational (Experimental) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services, Medicine, Policy No. M-149

Clinical Trials and Investigational Device Exemption (IDE) Studies, Medicine, Policy No. M-150

Peripheral Nerve Stimulation (PNS) and Peripheral Nerve Field Stimulation (PNFS), Surgery, Policy No. M-205

Responsive Neurostimulation, Surgery, Policy No. M-216

REFERENCES

1. Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §40.4 - Items Covered Under Warranty
2. Medicare Claims Processing Manual, Chapter 32 - Billing Requirements for Special Services, §50 – Deep Brain Stimulation for Essential Tremor and Parkinson's Disease

CODING

Codes	Number	Description
CPT	61850	Twist or burr hole(s) for implantation of neurostimulator electrode(s), cortical
	61860	Craniectomy or craniotomy for implantation of neurostimulator electrodes, cerebral, cortical
	61863	Twist drill, burr hole, craniotomy, or craniectomy for stereotactic implantation of neurostimulator 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 for stereotactic implantation of neurostimulator 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 for stereotactic implantation of neurostimulator array in subcortical site (e.g., thalamus, globus pallidus,

Codes	Number	Description
		subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; first array
	61868	Twist drill, burr hole, craniotomy, or craniectomy for stereotactic implantation of neurostimulator 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 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
	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 physician attendance
	95962	; each additional hour of physician attendance (List separately in addition to code for primary procedure) (Use 95962 in conjunction with code 95961)
	95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neuromodulation, 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
	95971	; 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	; 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	C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
	C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
	L8679	Implantable neurostimulator, pulse generator, any type
	L8680	Implantable neurostimulator electrode, each

Codes	Number	Description
	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 *(Code non-covered by Medicare – see L8679)*
	L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension *(Code non-covered by Medicare – see L8679)*
	L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension *(Code non-covered by Medicare – see L8679)*
	L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension *(Code non-covered by Medicare – see L8679)*
	L8689	External recharging system for battery (internal) for use with implantable neurostimulator

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*