Molina Clinical Policy
Deep Brain Stimulation (DBS) for Epilepsy: Policy No. 335

Last Approval: 2/9/2022
Next Review Due By: February 2023

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Seizures and Epilepsy

Epilepsy is a common neurological disease with a prevalence of approximately 3 million adults and 470,000 children. Management typically includes antiepileptic drugs (AEDs) however, nearly 30% of patients continue to experience uncontrolled seizures despite medical therapy. More complex procedures may be needed such as intracranial surgery or neurostimulation with deep brain stimulation (DBS) or vagus nerve stimulation (VNS) ([1] Hayes, 2021). Epilepsy is defined by one of the following (Jehi, 2018):

- Two or more unprovoked (or reflex) seizures occurring > 24 hours apart; or
- One unprovoked (or reflex) seizure with high risk of recurrence over the next 10 years defined as a high risk ≥ 60% that occurs after two unprovoked seizures; or
- Diagnosis of an epilepsy syndrome.

The lifetime prevalence of a seizure is approximately 10% however, many of these seizures do not advance to epilepsy. Seizures that are not likely epilepsy include provoked seizure which result from toxins, medications, drugs of abuse, or metabolic factors. In addition, single unprovoked seizure (without an increased risk of recurrent seizures) are also not likely to be epileptic in nature. (Jehi, 2018).

Prevalence of epilepsy in a lifetime is 2-3%. Types of seizures and epilepsy syndromes can be categorized by clinical presentation as well as by electroencephalogram (EEG) findings. (Jehi, 2018):

- **Generalized Seizures.** Includes tonic-clonic, absence, myoclonic, clonic, tonic, or atonic and typically present with impaired consciousness. The seizure may also present with partial awareness (such as with absence seizures with eyelid myoclonias or myoclonic seizures).
- **Focal Seizures (Partial Seizures).** Begins within networks limited to one hemisphere of the brain and includes localized symptoms. Seizures may evolve quickly into bilateral convulsive seizures; appearance may be similar to generalized onset tonic-clonic seizures; awareness may or may not be impaired.
- **Status Epilepticus (SE).** Categorized as five minutes or more of a continuous seizure or two or more discrete seizures without complete recovery of consciousness between seizures (these may occur with another seizure type).

Deep Brain Stimulation

Deep brain stimulation (DBS) may be considered as a supplement to antiepileptic medications for partial-onset seizures (with or without secondary generalization) that cannot be controlled with medical therapy only. The procedure encompasses intracranial implantation of electrodes which send an automated course of electrical stimulation to the anterior nucleus of the thalamus (ANT). This part of the brain is related to seizure propagation. Through stimulation or lesioning of the ANT, seizure frequency may be reduced as well as long-term effects caused by uncontrolled seizures. ([1] Hayes, 2021).

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FDA Approval

The Food and Drug Administration (FDA) approved DBS in 2018 as an adjunctive therapy for adults with partial-onset seizures who are refractory to three or more antiseizure medications. (Sirven, 2021). The Medtronic DBS System for Epilepsy (Product Code: MBX) was approved to deliver DBS of the anterior nucleus of the thalamus (ANT) in patients with drug-resistant epilepsy ([1] Hayes, 2021) and may reduce the frequency of seizures in patients ages 18 and diagnosed with epilepsy characterized by partial-onset seizures (seizures originating from one cerebral hemisphere), with or without secondary generalization (spreading to the other hemisphere), that are refractory to three or more antiepileptic medications. ([1] FDA, 2018). Medical literature includes data on long-term follow-up over several years in study patients. A reduction of 40% in the three months following treatment with DBS was found; those who had a long-term follow-up under seven years saw a decrease of 75%. Severity of seizures also were reported as well as an increased quality of life. Cognitive function also improved in some; depression also did not worsen significantly. (Epilepsy Foundation, 2018).

The procedure includes connecting leads to an extension; the extensions are connected to a single neurostimulator that is implanted in a subcutaneous pocket. The neurostimulator provides mild electrical stimulation to the targeted area in the brain which is thought to override neuronal activity thereby reducing seizure frequency. Patients also receive a hand-held Intercept™ Patient Therapy Programmer it is an external device that allows the patient to control therapy that is delivered within physician-prescribed parameters. Stimulation may be programmed and adjusted non-invasively by the clinician to maximize symptom control and minimize side effects. ([1] FDA, 2018).

Device Types

Activa

There are two types of Activa neurostimulators. The **Activa PC** is a dual channel device that delivers stimulation to one or both sides of the brain using two lead wires; it has a non-rechargeable battery ([1] Medtronic, 2017). The **Activa RC** neurostimulator is a rechargeable deep brain stimulation device. Expected longevity is 15 years of longevity and MRI accessible under certain conditions – it also works with the SenSight™ Directional Lead System (see below for more information) ([2] Medtronic, 2021).

Percept™

The Percept™ System was approved by the FDA in June 2020 ([3] FDA, 2020). The device is the next generation of the Activa PC; Percept PC features BrainSense™ technology to record brain signals using the implanted directional sensing DBS lead. Signals can be recorded while delivering therapeutic stimulation. Information is recorded and used to guide treatment. Battery life is >5 years and MRI accessible under certain conditions ([3] Medtronic, 2020). The Percept device allows for more customized therapy and allows Providers to treat epilepsy and record electrical activity from deep in the brain (Yale, 2021).

In 2020, the manufacturer issued a recall for Percept™ due to a software anomaly in the A620 Patient Programmer application. This resulted in failure to connect with the Percept PC device. Starting in November 2020, those impacted were notified and a recall notification letter was sent. ([4] FDA, 2020). Starting in March 2021, additional notification was sent describing the issues and provided a workaround to use until a software update is available. This impacted an estimated 5300 downloads worldwide ([5] FDA, 2020).

SenSight

The SenSight directional DBS lead system received FDA approval on May 25, 2021 ([6] FDA, 2021). The device is a first-of-its-kind and combines the benefits of directionality with sensing power. SenSight™ directional lead and SenSight™ extension work with the Percept™ PC neurostimulator which can enhance the detection of local field potentials (LFPs). These LFPs are are 1 million times smaller than DBS stimulation pulses. ([4] Medtronic, 2021).

COVERAGE POLICY

The Medtronic Deep Brain Stimulation (DBS) System for Epilepsy **is considered experimental, investigational, and unproven** for the treatment of epilepsy due to insufficient evidence in the peer reviewed literature.

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SUMMARY OF MEDICAL EVIDENCE

Studies conducted on DBS for epilepsy (including short-term open-label and small sham-controlled) found that stimulation in these regions can decrease seizure frequency by over 50%. The SANTE trial was a randomized clinical trial of DBS in the anterior nucleus of the thalamus; it included 110 patients with drug resistant epilepsy. Patients receiving stimulation therapy reported a 29% reduction in seizure frequency (compared with sham stimulation at three months, 54% reported less seizures of at least 50% by two years in the unblinded phase). The most significantly reduced seizures were complex partial and "most severe". A long-term follow-up study was conducted of the same trial; response rate was 68% at five years which equated to 59 patients (with complete seizure diary information). Results indicate a decrease in seizures and improved quality of life improved over time. No unanticipated adverse events were reported. Rates of depression, suicidality and Sudden Unexpected Death in Epilepsy (SUDEP) were comparable to rates of those with general refractory epilepsy. (Sirven, 2021).

Li et al. (2018) performed a systematic review that included 10 randomized controlled trial (RCTs) and 48 uncontrolled studies. Summaries were discussed by area of the brain targeted by DBS. A review showed that DBS may be effective in reducing seizures when DBS targets the ANT or hippocampus. Across studies, over 70% of patients experienced a reduction in seizures by 50% or more. However, there are very few RCTs; observational studies had small sample sizes. Individual responses varied depending on seizure syndrome, presence or absence of structural abnormalities, and electrode position. Results were inconclusive when DBS targeted the centromedian nucleus of the thalamus, the cerebellum, and the subthalamic nuclei. Safety data is limited due to the small population sizes. Meta-analyses were also not performed.

Fisher et al. (2010) reported a multi-center, double-blind, randomized trial of bilateral stimulation of the anterior nuclei of the thalamus for localization-related epilepsy (SANTE Trial). Subjects were adults with medically refractory partial seizures, including secondarily generalized seizures. A total of 110 subjects were randomized. Half received stimulation and half no stimulation during a three-month blinded phase; all received unblinded stimulation. Baseline monthly median seizure frequency was 19.5. In the last month of the blinded phase, the stimulated group had a 29% greater reduction in seizures compared with the control group, as estimated by a generalized estimating equations (GEE) model. Unadjusted median declines at the end of the blinded phase were 14.5% (control group) and 40.4% (stimulated group). Complex partial and "most severe" seizures were significantly reduced by stimulation. By two years, a 56% median percent reduction in seizure frequency was reported; 54% of patients had a seizure reduction of at least 50% and 14 patients were seizure-free for at least six months. Two subjects had acute, transient stimulation-associated seizures. Cognition and mood showed no group differences, but subjects in the stimulated group were more likely to report depression or memory problems as adverse events. Complication rates were modest. Five deaths occurred but were not due to implantation or stimulation. Symptomatic hemorrhage or brain infection were not reported. It was concluded that bilateral stimulation of the anterior nuclei of the thalamus reduces seizures; benefits persisted for two years of study. DBS of the ANT is useful for some people with medically refractory partial and secondarily generalized seizures, however more studies are needed to determine long-term benefits.

Troster et al. (2017) assessed neuropsychological adverse events from the SANTE trial during the three-month blinded phase and at seven-year follow-up during the open-label noncomparative phase. At baseline, there were no differences in depression history between groups. During the three-month blinded phase, depression was reported in eight (15%) patients from the stimulation group and in one (2%) patient from the no stimulation group. Memory adverse events also occurred at significantly different rates between the treatment groups during the blinded phase (seven in the active group, one in the control group).

Salanova et al. (2015) reported long-term outcomes of the SANTE trial (see Troster et al., 2017 above). The uncontrolled open-label portion of the trial began after three months and beginning at 13 months; stimulation parameters could be adjusted at the clinician's discretion. Of 110 implanted patients, 105 (95%) completed the 13-month follow-up, 98 (89%) completed the three-year follow-up, and 83 (75%) completed the five-year follow-up. Among patients with at least 70 days of diary entries, the median change in seizure frequency from baseline was 41% at one

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year and 69% at five years. During the study, 39 (35%) of 110 patients had a device-related serious adverse event, most of which occurred in the first several months after implantation. Frequently reported serious adverse events among patients included implant site infection (10%) and lead(s) not within target (8.2%). Seven deaths occurred during the study however none were considered device-related. Depression was reported in 41 patients (37%); this was considered device related in three cases. Thirty patients (27%) reported non-serious memory impairment during the study, half of which had a history of the condition. While some patients appear to have benefited from treatment during the extended follow-up phase, the difference between groups in the blinded portion of the study was significant but overall modest.

Cukiert et al. (2017) conducted a double-blind, placebo-controlled randomized trial evaluating 16 patients with refractory temporal lobe epilepsy. Prior to treatment, patients had focal impaired awareness seizures (FIAS) or complex partial seizures; 87% had focal aware seizures (FAS) or simple partial seizures. All patients underwent DBS device implantation and were followed for six months. Patients were seen weekly to receive treatment or placebo. Patients kept a seizure diary during the study period. To maintain double-blind status, programming was performed by a non-treating assistant. Patients were considered seizure-free if no seizures occurred during the last 2 months of the trial. Responders were defined as patients experiencing a reduction of 50% or more in frequency reduction. There was a significant difference in FIAS frequency from the first month of full stimulation until the end of the blinded phase and FAS frequency for the same period except for the third month of the blinded phase.

Sprengers et al. (2017) updated a 2014 review to assess the safety, efficacy and tolerability of DBS and cortical stimulation in patients with refractory epilepsy. Reviews included RCTs comparing DPS to sham stimulation, resective surgery or further treatment with antiepileptic drugs. Of the 10 RCTs identified for inclusion in the 2014 review, three trials were specific to DBS (1 anterior thalamic DBS trial [n=109]; and two centromedian thalamic DBS trials [n=20] over 40 treatment periods). The 2017 update included a cross-over RCT of bilateral anterior thalamic stimulation (n=4) and a double blind RCT of hippocampal stimulation (n=6) that was not included in the meta-analysis due to missing detailed methodology. Primary outcome measures included the proportion of patients who were disease free and a 50% or greater reduction in seizure frequency after one to three months. The evidence was rated as moderate quality and no statistical or clinically significant differences were reported based upon the primary outcome measures. Authors concluded that there is insufficient evidence upon which to draw conclusions regarding the efficacy and safety of hippocampal DBS or centromedian DBS as a treatment for epilepsy.

The medical literature does not support DBS as an adjunct therapy for refractory epilepsy; this is largely attributed to study limitations as well as minimal outcome measures. However, seizure frequency decreased in patients treated with DBS for refractory epilepsy *with partial-onset seizures (with or without secondary generalization).* Seizure severity may also be reduced and quality of life improved. Serious adverse events were noted but were not severe enough to cease DBS treatment. Further research is needed. ([1] Hayes, 2021).

Future Research

An *Evolving Evidence Review* for the Neuropace RNS System (Neuropace Inc.) was published regarding its use for the treatment of drug-resistant epilepsy. The device is intended for patients age 18 or older with partial onset seizures who have also completed diagnostic testing (including localizing no more than 2 epileptogenic foci; patient is refractory to 2 or more antiepileptic medications; and the patient has current, frequent, disabling seizures. The NeuroPace RNS system is FDA approved (PMA #P100026) for the treatment of specific types of seizures including motor partial seizures, complex partial seizures, and secondarily generalized seizures. The medical literature demonstrates minimal support for the use of the NeuroPace RNS system for the treatment of drug-resistant epilepsy. Studies include one RCT that indicates greater seizure reduction than with sham at 3 to 4 months follow-up. A long-term open-label follow-up suggests benefits however the study lacked a control group. No systematic reviews or clinical guidelines have been published for the Neuropace RNS System. ([2] Hayes, 2021).

National and Specialty Organizations

The **American Academy of Neurology (AAN)** and the **American Epilepsy Society (AES)** published the *Evidence-Based Guideline: Management of an Unprovoked First Seizure in Adults* (2015). A *Summary of Evidence-Based Guideline for Clinicians* was also published in 2015. Recommendations include:

- Patients with an unprovoked first seizure should be informed that the risk of seizure recurrence is greatest early within the first two years; clinical variables related to an increased risk may include a prior brain insult, an EEG with epileptiform abnormalities, a significant brain-imaging abnormality, and a nocturnal seizure.
- Immediate AED therapy (versus delay of treatment pending a second seizure) reduce seizure recurrence risk within the first two years but may not improve quality of life. Immediate AED treatment is unlikely to improve prognosis over a longer timeframe as measured by sustained seizure remission.
- Patients should be informed that AED adverse events (AEs) may occur in 7-31% and that AEs are likely mild and reversible. Providers should base the initiation of immediate AED treatment following a first seizure on individualized assessments to evaluate the risk of recurrence against the AEs of AED therapy and patient preferences following education and discussion. In addition, patients should be informed that immediate treatment will decrease seizure risk for the following two years, however, long-term prognosis for seizure remission is low.

The **National Institute for Health and Care Excellence (NICE)** (2020) provides the following guidance for DBS for refractory epilepsy in adults:

- Patient selection should involve a multidisciplinary team with experience in the management of epilepsy including a neurologist, neurophysiologist and neurosurgeon.
- The procedure should only be done in neurosurgery centers specializing in managing epilepsy.

Additional research is needed to describe patient selection and define the target area of the brain. Outcomes to include are reduction in seizure frequency and improvement in the epilepsy seizure outcome scale, quality of life, reduction in concomitant medication and hospital admissions.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT	Description
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	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	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 2 or more electrode arrays
95970	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (e.g., cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without programming
95983	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 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-hyphento-hyphen face time with physician or other qualified health care professional

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95984	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 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-hyphento-hyphenface time with physician or other qualified health care professional (list separately in addition to code for primary procedure)

HCPCS Codes

HCPCS	Description
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, rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, 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

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APPROVAL HISTORY

2/9/2022	Policy reviewed, no changes to coverage, updated references.
2/8/2021	Policy reviewed, no changes.
4/23/2020	Policy reviewed, no changes.
3/11/2019	New policy.

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

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