

Molina Clinical Policy

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

Last Approval: 2/8/2023

Next Review Due By: February 2024



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

Drug-resistant epilepsy (DRE), also referred to as intractable, medically refractory, or pharmacoresistant epilepsy, is used to characterize patients with epilepsy whose seizures do not effectively respond to anti-epileptic medications (Sirven, 2022). Medically refractory epilepsy may affect up to 20 to 40% of epileptic patients, or about 400,000 persons in the United States (NINDS, 2018; Sirven, 2022). Epilepsies presenting with partial/focal-onset seizures, especially those associated with temporal lobe epilepsy, are over-represented amongst DRE (Asadi-Pooya et al., 2017; Gummadvelli et al., 2022). Resective epilepsy surgery is the preferred treatment for DRE patients. Recent International League Against Epilepsy expert consensus recommendations support early referral for epilepsy surgery for patients with DRE (if adherent to management) up to 70 years of age, as soon as drug resistance is established and regardless of epilepsy duration, seizure type, epilepsy type, localization, or comorbidities (Jehi et al., 2022). However, when surgery is contraindicated or ineffective, deep brain stimulation has emerged as a treatment option.

Deep brain stimulation (DBS), a neurointerventional procedure and form of stereotactic brain surgery, involves implanting electrodes and a pacemaker-like device to transmit electrical pulses to areas of the brain as an adjunctive treatment for several neurological conditions, including epilepsy. The electrodes are attached to a pulse generator and delivers a predetermined (open loop) program of electrical stimulation to deep brain structures to the anterior nucleus of the thalamus, which is located at the anterior and superior aspect of the thalamus. The ANT is a crucial component of the Papez circuit which regulates emotional reactions and contributes to the propagation of seizures. Stimulation or lesioning of the ANT alter electroencephalography (EEG) and reduces seizure activity in animal epilepsy models (Bouwens et al. 2019). The electrode leads are implanted unilaterally or bilaterally in the ANT using small entry sites and stereotactic targeting procedures, followed by the placement of a neurostimulator device or implantable pulse generator beneath the patient's collarbone skin. DBS for DRE is conducted under local or general anesthesia and usually takes up to seven hours to complete (Zangiabadi et al. 2019). A multidisciplinary team of neurosurgeons, neurologists, nurses, and technical support personnel are necessary to assess the patient's eligibility, perform the DBS procedure and confirm electrode placement, then monitor and follow up with the patient after surgery (Zangiabadi et al. 2019). Adverse effects of DBS include long-term presence of a brain implant which increases the risk of infection (2.8-6.1%), lead migration or misplacement (5.1%), and skin erosion (1.3-2%), among other clinical events. In addition, depending on the targeted brain area, stimulation has been linked to a range of adverse cognitive, behavioral, psychiatric, and psychosocial side effects (Maslen et al. 2018).

Regulatory

DBS is a procedure and thus not regulated by the FDA. Any medical devices, drugs, and/or tests used as part of this procedure, on the other hand, may be subject to FDA regulation.

The Medtronic DBS System for Epilepsy is the only FDA-approved DBS system for the ANT in patients with DRE. The FDA authorized the Medtronic DBS System for Epilepsy (Medtronic, Inc) under the Premarket Approval process in 2018 (based on the SANTÉ pivotal trial). The intended use is bilateral stimulation of the ANT 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 Medtronic DBS System for Epilepsy has demonstrated safety and effectiveness for patients who

Molina Clinical Policy

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

Last Approval: 2/8/2023

Next Review Due By: February 2024



average six or more seizures per month over the three most recent months prior to implant of the DBS system (with no more than 30 days between seizures). The Medtronic DBS System for Epilepsy has not been evaluated in patients with less frequent seizures ([Medtronic, 2023](#)). The main components of the device include the implantable Active PC neurostimulator, leads, extension, external neurostimulator, clinician programmer, and patient programmer (FDA, 2018).

Summary: Although the available peer-reviewed evidence on the use of DBS for epilepsy is largely limited to the findings of the SANTE study, this procedure has become more widely used despite concerns about potential significant procedure-related, device-related, or stimulation related adverse events (AEs). Continued research using well-designed controlled studies are required to confirm the findings of the pivotal RCT, to determine the best DBS treatment parameters, and to establish which patients would most benefit from this therapy. In a clinical setting, however, the risks of inadequately managed epilepsy and recurrent seizures are evaluated and considered alongside the potential benefits, which may outweigh the associated risks. The current consensus indicates that this alternative treatment results in reductions of seizure frequency in a subset of patients as reviewed in the literature, such as patients whose epilepsy has not responded to medications and resective surgery, or who are not candidates for resective surgery or other treatments.

DBS for chronic, medically refractory epilepsy is addressed in this policy. The policy does not address cortical stimulation in treatment-resistant epilepsy (e.g., NeuroPace® RNS® System)

COVERAGE POLICY

Unilateral or bilateral DBS of the anterior nucleus of the thalamus **may be considered medically necessary** when **ALL** of the following clinical criteria with documentation are met:

1. Definitive diagnosis of focal partial onset seizures with or without generalized seizure; **AND**
2. Average of 6 or more seizures per month during the previous 3 months, with no more than 30 days between seizures; **AND**
3. Refractory to **THREE** or more adequately dosed antiepileptic; **AND**
4. Ineligible for resective surgery OR has failed vagus nerve stimulation or resective surgery; **AND**
5. 18 years of age or older; **AND**
6. Absence of progressive neurological or medical conditions such as brain tumors or neurodegenerative disease; **AND**
7. No history of non-epileptic seizures; **AND**
8. Surgery is performed at a *Level 4 epilepsy center, in accordance with NAEC guidelines.
[*Epilepsy Center Locations and Designation \(NAEC, 2023\)](#)

LIMITATIONS AND EXCLUSIONS

The following are considered **contraindications/exclusions** based on insufficient evidence:

1. Anticipated to require transcranial magnetic stimulation (TMS) therapy in the future, as TMS therapy is contraindicated for patients with implanted DBS system; or
2. Unable, or do not have the necessary assistance to properly operate the DBS therapy patient programmer or charging system where applicable; or
3. Risk of an intracranial surgical procedure and/or general anesthesia are unacceptable due to an underlying medical condition.

The following are considered **experimental, investigational, and unproven** based on insufficient evidence:

1. Any indications other than those listed above

SUMMARY OF MEDICAL EVIDENCE

DBS has been proposed as a treatment for medically refractory epilepsy, which persists in severity and/or frequency despite a reasonable trial of two or more antiepileptic medications, as an alternative to resective surgery, and when cortical stimulation is unsuitable. Systematic reviews, meta-analysis, randomized controlled trials (RCTs) and case series support the safety and efficacy of DBS for the treatment of epilepsy (Salanova et al., 2021; Herrman et al., 2019; Chang and Xu, 2018; Li and Cook, 2018; Zhou et al., 2018; Sprengers et al., 2017; Troster et al., 2017; Salanova et al., 2015; Fisher et al., 2010).

RCTs that evaluated DBS of the ANT for adults with refractory epilepsy (Fisher et al. 2010; Herrman et al. 2019).

Fisher et al. (2010) published the findings of a multicenter, RCT of bilateral Stimulation of the Anterior Nuclei of Thalamus for Epilepsy (SANTE) trial. Prior to entering in the study, individuals had failed trials of at least three antiseizure drugs and had documented at least 6 seizures per month in a 3-month daily epileptic diary, but no more than 10 seizures per day. Participants were randomly assigned to one of two groups: stimulation on or stimulation off. The study implanted Medtronic DBS devices with electrodes in the ANT in 109 adult patients (n = 109) with medically refractory partial seizures, including secondarily generalized seizures. The trial was structured with a 3-month double-blinded phase, with a subsequent 9-month open-label follow-up period, with an additional data collection follow-up at 2, 3, 4, 5, and 7 years. Individuals in the intervention group received 5 volts with 145 pulses per second stimulation, with 1 minute on and 5 minutes off stimulation (intervention, N = 54); participants in the control condition received no stimulation during the 3-month blinded phase of the study (control, N = 54). Patients who received stimulation therapy reported a 29% greater reduction in seizure frequency compared with sham stimulation at three months and 54% of patients had a seizure reduction of at least 50% by two years in the unblinded phase. Complex partial seizures and "most severe" seizures were the most drastically reduced. Participants in the stimulated group reported higher depression (15 versus 2%), memory difficulties (13 versus 2%), as well as 14 implant site infections (13%), and five asymptomatic hemorrhages (5%). According to the authors, DBS of the anterior nuclei was mostly palliative in this population, but 14 participants (12.7%) were seizure-free for at least 6 months. Furthermore, significant improvements were observed in some subjects who had previously been unaided by multiple medications, VNS, or epilepsy surgery. It was concluded that "Additional clinical experience may help to establish the best candidates and stimulation parameters, and to further refine the risk–benefit ratio of this treatment."

Results from this double-blinded phase and the open-label follow-ups were reported in 3 publications (Salanova et al., 2015; Troster et al., 2017; Salanova et al. 2021)

- Salanova et al. (2015) in a long-term follow-up study of the same trial which began 13 months following device implantation, participants receiving active stimulation were followed for an additional 4 years. The results show a decrease in seizures and an improvement in quality of life (QOL) over time. The median percent seizure reduction from baseline at 1 year was 41%, and 69% at 5 years. The responder rate (greater than or equal to 50% reduction in seizure frequency) at 1 year was 43%, and 68% at 5 years. In the 5 years of follow-up, 16% of subjects were seizure-free for at least 6 months. It is noted that by the 5-year follow-up, 61 participants with active DBS implants had begun taking at least 1 new antiseizure drug that they had not taken at baseline. There were no unexpected adverse effects reported. Depression, suicidality, and SUDEP rates were comparable to those with general refractory epilepsy. The results of this study show that DBS has a significant long-term benefit for epileptic patients; however, the sample size was small, and the study was not blinded. Additional data from larger, blinded RCTs is necessary.
- Troster et al. (2017) assessed incidence of memory and depression AEs in the SANTE Trial blinded phase and their relationship to objective neurobehavioral measures, baseline characteristics, QOL and long-term neurobehavioral outcome. The neurobehavioral AE and neuropsychological data from the SANTE Trial were analyzed. A 7-year follow-up with 67 of the participants reported no statistically significant change in depression, anxiety, or memory between measure collection at baseline and 7 years after implantation. The authors concluded that, in a small number of patients, bilateral ANT DBS was associated with subjective depression and memory AEs during the blinded phase, but not with objective, long-term neurobehavioral worsening. Monitoring and neuropsychological assessment of depression and memory are recommended from a theoretical standpoint, as well because the active stimulation group experienced more memory and depression AEs than the control group.

Molina Clinical Policy

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

Last Approval: 2/8/2023

Next Review Due By: February 2024



The FDA granted pre-market approval to the Medtronic DBS Therapy System on April 27, 2018, based on the SANTE trial data for the treatment of epilepsy with bilateral stimulation of the ANT 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 antidiabetic medications.

Salanova et al. (2021), in a subgroup analysis with the 50 remaining participants at the 7-year follow-up, found that participants with and without prior vagal nerve stimulation (VNS) did not have significantly different median seizure reductions (median for group with VNS, 75%; N = 21; median for group without prior VNS, 78%; N = 29; between-group difference, $p > .05$). Participants at the 7-year follow-up with temporal lobe seizures reported a significant median seizure reduction of 78% (N = 35) compared to baseline; participants with frontal lobe seizures reported a nonsignificant median reduction of 86% (N = 9) compared to baseline; and participants with seizures in other regions reported a significant median reduction of 39% (N = 11) compared to baseline. The authors reported that the improvement in seizure severity score on the Liverpool Seizure Severity Scale (LSSS) found at 5 years remained stable (no statistics reported). By the 7-year follow-up, 77% of the 50 remaining participants had added at least 1 new antiseizure drug, and the authors reported that the trajectory of improvement in seizure frequency was similar between participants with and without added antiseizure drugs (no statistics reported).

Herrman et al. (2019) conducted a prospective, randomized, double-blind evaluation of the safety and efficacy of DBS for adult patients with focal DRE, with or without subsequent generalization, who were not candidates for resective surgery (N = 18). In the three months preceding to implantation, participants experienced an average of 53 seizures per month and had taken an average of 13 anticonvulsant medications (range: 5 to 15). The exclusion criteria were identical to those used in the SANTE study (Fisher et al., 2010). Participants were randomized after DBS device implantation to receive 5-volt stimulation through the devices (intervention, N = 8) or no stimulation (control, N = 10) for a 6-month blinded period. During the nonblinded open-label phase (months 7 through 12), all subjects received 5-volt stimulation; data obtained at 3, 6, 9, and 12 months focused on seizure frequency, seizure type, and adverse effects. The duration of this study was 12 months; however, participants received their randomized treatment for only the first six months. For the second six-month period, all participants got active treatment. At the conclusion of the blinded six-month period, the authors found no statistically significant changes between groups. During the open active vs therapy phase at 6-12 months, there was a 22% decrease in the frequency of all seizures compared to baseline ($p=0.009$). At the 12-month time point, four participants experienced a reduction in total seizure frequency of 50%, and five subjects experienced a reduction in focal seizure frequency of 50%. There was no evidence of a cumulative effect. LSSS at 6 months showed no significant differences between groups, however a slight, significant drop in LSSS was observed after all subjects had received stimulation for 6 months.

Vetkas et al. (2022) conducted a systematic review to assess the efficacy of DBS to the ANT, centromedian thalamic nucleus, and hippocampus. In total, 48 articles with 527 patients (sample sizes ranging from 3 to 81) met the inclusion criteria. The meta-analysis included 44 articles (23 for ANT, 8 for centromedian thalamic nucleus, and 13 for hippocampus) with a total of 527 patients. For the ANT, centromedian thalamic nucleus, and hippocampus, there were two, two, and three RCTs (including the SANTE trial) and 23, 8, and 13 total studies, respectively.

Zangiabadi et al. (2019) reviewed 20 small open-label, uncontrolled, pilot studies of DBS for refractory epilepsy with targets in the ANT (N = 127) and included the SANTE trial (discussed above). AEs in these small studies included: wound infection; lead or extension fracture; erosion; electrode migration; external interference with other devices; equipment infection; pain; transient worsening or new seizures; dizziness; hardware discomfort; and ineffective product.

Li et al. (2018) performed a systematic review that included 10 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 of 50% or more. However, there are very few RCTs, and observational studies had small sample sizes. Individual responses varied depending on seizure syndrome, the 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.

Sprengers et al. (2017) published a systematic review on deep brain and cortical stimulation for the treatment of medically refractory epilepsy in the Cochrane Collaboration. The evidence was limited to RCTs, with the only study evaluating DBS of the ANT being the blinded, sham controlled SANTE trial (n=109). At 3 months of follow-up, the

Molina Clinical Policy

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

Last Approval: 2/8/2023

Next Review Due By: February 2024



authors reported no significant difference in seizure freedom or responder rate. Moderate-quality evidence could not demonstrate statistically or clinically significant changes in the proportion of patients who were seizure-free or experienced a 50% or greater reduction in seizure frequency (primary outcome measures) after one to three months of anterior thalamic DBS. A statistically significant reduction in seizure frequency was found for anterior thalamic DBS (mean difference of -17.4% compared to sham stimulation); however, it was noted that both anterior thalamic DBS and responsive ictal onset zone (i.e., multifocal epilepsy) stimulation do not have a clinically meaningful impact on quality of life after three months of stimulation (high-quality evidence). The authors concluded that compared to sham stimulation, one to three months of anterior thalamic DBS ((multi)focal epilepsy), responsive ictal onset zone stimulation ((multi)focal epilepsy) and hippocampal DBS (temporal lobe epilepsy) moderately reduce seizure frequency in refractory epilepsy patients. However, it is noted that anterior thalamic DBS is associated with higher rates of self-reported depression and subjective memory impairment.

A health technology assessment (HTA) determined that potential but unproven benefit for the use of DBS of the ANT in adult patients diagnosed with epilepsy who have uncontrolled, partial-onset seizures (with or without secondary generalization) after ≥ 3 antiepileptic drugs. This rating is reflective of an overall low-quality body of evidence suggesting that DBS of the ANT may reduce seizure frequency and severity as well as improve QOL relative to sham DBS or baseline measures. The HTA noted that treatment response rates varied considerably and ranged from 22% to 85%, depending on the follow-up time, but seizure freedom was not maintained for the duration of any study. Treatment-related AEs may occur but are typically transient and generally did not necessitate discontinuation of DBS therapy or removal of DBS implanted devices. However, uncertainty exists regarding the effectiveness and safety of DBS in refractory epilepsy due to a limited number of comparative studies and small numbers of treated patients (Hayes, 2022).

National and Specialty Organizations

American Academy of Neurology (AAN) and the American Epilepsy Society (AES)

No guidelines were identified from the AAN or AES on DBS for treatment of epilepsy.

American Society for Stereotactic and Functional Neurosurgeons (ASSFN) guidelines state neuromodulation treatments including DBS expand the surgical options for epilepsy patients and provide options for patients who are not candidates for resective surgery. It notes that DBS of the bilateral ANT is an FDA approved, safe and efficacious treatment option for patients with refractory focal epilepsy (ASSFN, 2022).

National Institute for Health and Care Excellence (NICE) published DBS guidance for patients with refractory epilepsy in August 2020, and a review is scheduled in 2023. Due to the limited quantity and quality of published evidence, the recommendations in this guidance state that individuals with refractory epilepsy and anterior thalamic targets should only undergo DBS under special arrangements for clinical governance, consent, audit, and research. NICE recommends special arrangements when the independent advisory committee determines that there is ambiguity about the safety and effectiveness of certain procedures.

The guidance also suggests that patient selection should involve a multidisciplinary team with experience in the management of epilepsy including a neurologist, neurophysiologist and neurosurgeon, and that 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, QOL, reduction in concomitant medication and hospital admissions.

SUPPLEMENTAL INFORMATION

None.

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

Last Approval: 2/8/2023
 Next Review Due By: February 2024



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	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 (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
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 (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-to-face time with physician or other qualified health care professional
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-to-face 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, nonrechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension

Molina Clinical Policy

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

Last Approval: 2/8/2023

Next Review Due By: February 2024



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

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

02/08/2023	Policy revised. Coverage position updated from 'experimental, investigational, and unproven for the treatment of epilepsy' to medically necessary if all criteria are met. Criteria for coverage added to the coverage policy section. The overview, summary of evidence, and references are revised and updated accordingly.
02/09/2022	Policy reviewed, no changes to coverage, updated references.
02/08/2021	Policy reviewed, no changes.
04/23/2020	Policy reviewed, no changes.
03/11/2019	New policy. IRO Peer Review. Policy reviewed on November 11, 2019 by a practicing, board-certified physician in the area of Neurology.

REFERENCES

Government Agencies

- Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Available from [CMS](#). Accessed January 2023.
*National Coverage Determination (NCD) for Electrical Nerve Stimulators (160.7) effective August 7, 1995. The DBS section of the NCD does not address its use for the treatment of epilepsy.
- United States Food and Drug Administration (FDA). Accessed January 2023.
 - Summary of safety and effectiveness data (SSED): Premarket Approval Application (PMA) P960009/S219. Notice of Approval April 27, 2018. Available from [FDA](#).
 - Premarket approval application (PMA): Medtronic DBS therapy for epilepsy (P960009/S219). Decision Date April 27, 2018. Available from [FDA](#).
 - Premarket approval application (PMA): Medtronic Master Percept and Activa deep brain stimulation (DBS) systems. Decision Date June 24, 2020. Available from [FDA](#).
 - Class 2 device recall Percept PC implantable neurostimulator (INS). Available from [FDA](#). Create Date December 16, 2020.
 - Class 2 Device Recall A610. Available from [FDA](#). Create Date April 7, 2021.
 - Premarket approval (PMA) database (search "SenSight"). Available from [FDA](#).

National and Specialty Organizations

- Gummadavelli A, Englot DJ, Schwab JM, et al. American Society for Stereotactic and Functional Neurosurgeons. ASSFN Position Statement on Deep Brain Stimulation for Medication-Refractory Epilepsy. *Neurosurgery*. 2022 May 1;90(5):636-641. doi: 10.1227/neu.0000000000001923. PMID: 35271523; PMCID: PMC9514731.
- Jehi L, Jette N, Kwon CS, et al. Timing of referral to evaluate for epilepsy surgery: Expert Consensus Recommendations from the Surgical Therapies Commission of the International League Against Epilepsy. *Epilepsia* 2022; 63:2491.
- National Institute for Health and Care Excellence (NICE). Deep brain stimulation for refractory epilepsy in adults [IPG678]. Available from [NICE](#). Published August 12, 2020. Accessed January 2023.
- National Association of Epilepsy Centers (NAEC). All Epilepsy Center Locations. Available from [National Association of Epilepsy Centers](#). Accessed January 2023.

Evidence Based Reviews and Publications

- Hayes. Registration and login required. Accessed January 2023.
 - Health Technology Assessment: Deep Brain Stimulation of the Anterior Nucleus of the Thalamus for Treatment of Refractory Epilepsy. Available from [Hayes](#). Published November 14, 2019. Updated Dec 29, 2022.
 - Evolving Evidence Review: Neuropace RNS System (Neuropace Inc.) for treatment of drug-resistant epilepsy. Available from [Hayes](#). Published September 7, 2021.
- DynaMed. Epilepsy in Adults. EBSCO Information Services. Accessed January 23, 2023. Available from: [Dynamed](#). Registration and login required.
- Sirven JI. Evaluation and management of drug-resistant epilepsy. Available from [UpToDate](#). Updated Dec 12, 2022.. Accessed January 2023. Topic 2214 Version 60.0. Registration and login required.
- Vetkas A, Fomenko A, Germann J, et al. Deep brain stimulation targets in epilepsy: Systematic review and meta-analysis of anterior and centromedian thalamic nuclei and hippocampus. *Epilepsia*. 2022 Mar;63(3):513-524. doi: 10.1111/epi.17157. Epub 2022 Jan 3. Erratum in: *Epilepsia*. 2022 Jun;63(6):1605. PMID: 34981509.

Molina Clinical Policy

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

Last Approval: 2/8/2023

Next Review Due By: February 2024



Peer Reviewed Publications

1. Asadi-Pooya A, Stewart G, Abrams D, Sharan A. Prevalence and Incidence of Drug-Resistant Mesial Temporal Lobe Epilepsy in the United States. *World Neurosurg.* Mar 2017;99:662-666. doi: 10.1016/j.wneu.2016.12.074.
2. Bouwens van der Vlis TAM, Schijns OEMG, Schaper FLWVJ, et al. Deep brain stimulation of the anterior nucleus of the thalamus for drug-resistant epilepsy. *Neurosurg Rev.* 2019 Jun;42(2):287-296. doi: 10.1007/s10143-017-0941-x. Epub 2018 Jan 6. PMID: 29306976; PMCID: PMC6502776.
3. Chang B, Xu J. Deep brain stimulation for refractory temporal lobe epilepsy: a systematic review and meta-analysis with an emphasis on alleviation of seizure frequency outcome. *Childs Nerv Syst.* 2018 Feb;34(2):321-327. doi: 10.1007/s00381-017-3596-6. Epub 2017 Sep 18. PMID: 28921161.
4. Fisher, R, Salanova, V, Witt, T, et al. Electrical stimulation of the anterior nucleus of thalamus for treatment of refractory epilepsy *Epilepsia.* 2010 May;51(5):899-908. doi: 10.1111/j.1528-1167.2010.02536.x.
5. Herrman H, Egge A, Konglund AE, Ramm-Petersen J, Dietrichs E, Tauboll E. Anterior thalamic deep brain stimulation in refractory epilepsy: a randomized, double-blinded study. *Acta Neurol Scand.* 2019;139(3):294-304. doi: 10.1111/ane.13047
6. Li MCH, Cook MJ. Deep brain stimulation for drug-resistant epilepsy. *Epilepsia.* 2018 Feb;59(2):273-290. doi: 10.1111/epi.13964
7. Maslen H, Cheeran B, Pugh J, Pycroft L, et al. Unexpected Complications of Novel Deep Brain Stimulation Treatments: Ethical Issues and Clinical Recommendations. *Neuromodulation.* 2018 Feb;21(2):135-143. doi: 10.1111/ner.12613. Epub 2017 May 30. PMID: 28557242; PMCID: PMC5811790.
8. Salanova V, Witt T, Worth R, et al. Long-term efficacy and safety of thalamic stimulation for drug-resistant partial epilepsy. *Neurology.* 2015 Mar 10;84(10):1017-25. doi: 10.1212/WNL.0000000000001334.
9. Salanova V, Sperling MR, Gross RE, et al. The SANTÉ study at 10 years of follow-up: Effectiveness, safety, and sudden unexpected death in epilepsy. *Epilepsia.* 2021 Jun;62(6):1306-1317. doi: 10.1111/epi.16895. Epub 2021 Apr 8. PMID: 33830503.
10. Sprengers M, Vonck K, Carrette E, Marson AG, Boon P. Deep brain and cortical stimulation for epilepsy. *Cochrane Database Syst Rev.* 2017 Jul 18;7(7):CD008497. doi: 10.1002/14651858.CD008497.pub3.
11. Tröster AI, Meador KJ, Irwin CP, Fisher RS, SANTE Study Group. Memory and mood outcomes after anterior thalamic stimulation for refractory partial epilepsy. *Seizure.* 2017 Feb;45:133-141. doi: 10.1016/j.seizure.2016.12.014.
12. Zangiabadi N, Ladino LD, Sina F, Orozco-Hernández JP, Carter A, Téllez-Zenteno JF. Deep Brain Stimulation and Drug-Resistant Epilepsy: A Review of the Literature. *Front Neurol.* 2019 Jun 6;10:601. doi: 10.3389/fneur.2019.00601. PMID: 31244761; PMCID: PMC6563690.

Manufacturer Website and Publications

Medtronic. Activa PC neurostimulator. Available from [Medtronic](#). Updated October 2022. Accessed January 2023.

APPENDIX

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