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

**Last Approval: 02/14/2024**
**Next Review Due By: February 2025**

## 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

Epilepsy is one of the most common neurological conditions worldwide characterized by recurrent seizures. Seizures are defined as paroxysmal disorders of the central nervous system characterized by abnormal cerebral neuronal discharge, with or without loss of consciousness. Most seizures can be categorized as either focal or generalized according to whether the onset of electrical activity involves both sides or a focal region of the brain. Epilepsy has a myriad of causes, such as brain tumors, metabolic disorders, hypoxic brain injuries, strokes, infections, and certain genetic syndromes; however, most cases are idiopathic in origin. Anti-epileptic medications are the first line of defense in treating the seizure disorder, however, many cases remain uncontrolled even in the setting of a rigorous drug regimen. Since epilepsy carries an increased risk for premature death, controlling the condition is paramount to patient's overall health and wellbeing.

**Refractory epilepsy,** also referred to as intractable or drug-resistant epilepsy, is used to characterize patients with epilepsy whose seizures do not effectively respond to anti-epileptic medications. Refractory epilepsy may affect up to 20 to 40% of epileptic patients, or about 400,000 persons in the United States, the majority of which present with partial/focal-onset seizures, especially those associated with temporal lobe epilepsy (Gummadavelli et al. 2022; Sirven 2022). Recent International League Against Epilepsy expert consensus recommendations support early referral for epilepsy resective surgery for patients with refractory epilepsy as soon as drug resistance is established, regardless of epilepsy duration, seizure type, epilepsy type, localization, or comorbidities (Jehi et al. 2022). When surgery is contraindicated or ineffective, however, deep brain stimulation has emerged as a treatment option.

**Deep brain stimulation (DBS)** is a form of stereotactic brain surgery. This neurointerventional procedure involves implanting electrodes and a device that transmits 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 (ANT), 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. A multidisciplinary team of neurosurgeons, neurologists, nurses, and technical support personnel are necessary to assess the patient's eligibility, perform the DBS procedure, confirm electrode placement, monitor post-procedure, and follow up with the patient after surgery. Adverse effects of DBS include increased risk of infection (2.8-6.1%), lead migration or misplacement (5.1%), and skin erosion (1.3-2%), among other clinical events such as cognitive, behavioral, and psychiatric side effects depending on the targeted brain area (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.

Medtronic Inc's (Minneapolis, MN) Activa Deep Brain Stimulation Therapy System is the only FDA approved DBS system for patients with refractory epilepsy. This device was given an FDA Pre-Market approval for the indication of "an adjunctive therapy (used along with medications) that delivers electrical stimulation to an area in your brain to reduce the frequency of seizures" on April 27, 2018, under the product code MBX (Stimulator, thalamic, epilepsy, implanted).

## COVERAGE POLICY

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

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

### LIMITATIONS AND EXCLUSIONS

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

1. Anticipated to require transcranial magnetic stimulation therapy in the future, as transcranial magnetic stimulation therapy is contraindicated for patients with implanted DBS system
2. Unable, or do not have the necessary assistance to properly operate the DBS therapy patient programmer or charging system where applicable
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

Peltola et al. (2023) conducted an analysis of the MORE multicenter patient registry to evaluate the safety and efficacy of anterior thalamic nucleus deep brain stimulation (ANT-DBS) in a real-world setting two years post implantation. Of the 170 patients with drug resistant focal epilepsy implanted with DBS therapy, 38% of patients reported cognitive impairment at baseline. The median monthly seizure frequency decreased by 33.1% from 15.8 at baseline to 8.8 at 2 years ($p < 0.0001$) with 32.3% responder rate. In the subgroup of 47 patients who completed 5 years of follow-up, the median monthly seizure frequency decreased by 55.1% from 16 at baseline to 7.9 at 5 years ($p < 0.0001$) with 53.2% responder rate, which is consistent with the SANTE study results that suggested seizure frequency continued to decrease after five years. The most frequently reported adverse events were increased frequency/severity in seizures (16%), memory impairment (patient-reported complaint, 15%), depressive mood (patient-reported complaint, 13%). Thirty-nine percent of the memory impairment complaints and 44% of the depressive mood complaints were related to worsening of preexisting conditions per site assessment. During the second year of follow up there was one definite sudden unexpected death in epilepsy case reported. High-volume centers (>10 implantations) had 42.8% reduction in median monthly seizure frequency by 2 years in comparison with 25.8% in low-volume center. In conclusion, ANT-DBS is effective at reducing seizure frequency in those with refractory epilepsy, especially if the patient can be treated at a high-volume epilepsy center.

Haneef and Skrehot (2023) conducted a systematic review and meta-analysis to evaluate neurostimulation in generalized epilepsy with the goal of assessing which treatment modality, vagal nerve stimulation (VNS), deep brain stimulation, or responsive neurostimulation (RNS), revealed better clinical results in those with refractory epilepsy. A

total of 20 studies were included in the analysis and data was pooled using a random-effects model using the meta package in R. Sufficient data for meta-analysis were available from seven studies for VNS (n = 510) and nine studies for DBS (n = 87). Data from RNS (five studies, n = 18) were insufficient for meta-analysis. The mean (SD) follow-up durations were as follows: VNS, 39.1 (23.4) months; DBS, 23.1 (19.6) months; and RNS, 22.3 (10.6) months. Meta-analysis showed seizure reductions of 48.3% (95% confidence interval [CI] = 38.7%-57.9%) for VNS and 64.8% (95% CI = 54.4%-75.2%) for DBS (p = .02). The authors concluded that the use of DBS may lead to greater seizure reduction than VNS in generalized epilepsy. Results from RNS use are promising, but further research is required.

Touma et al. (2022) conducted a systematic review and meta-analysis evaluating the mean percentage of seizure frequency decrease as compared to baseline, as well as proportion of treatment responders and those with seizure freedom. Thirty studies were included, 6 of which were RCTs. At long-term follow-up (mean 1.3 years), five observational studies for VNS reported a pooled mean percentage decrease in seizure frequency of 34.7% (95% confidence interval [CI]: -5.1, 74.5). In the open-label extension studies for RNS, the median seizure reduction was 53%, 66%, and 75% at 2, 5, and 9 years of follow-up, respectively. For DBS, the median reduction was 56%, 65%, and 75% at 2, 5, and 7 years, respectively. The proportion of individuals with seizure freedom at last follow-up increased significantly over time for DBS and RNS, whereas a positive trend was observed for VNS. Quality of life was improved in all modalities. The most common complications included hoarseness, and cough and throat pain for VNS and implant site pain, headache, and dysesthesia for DBS and RNS. The authors concluded that neurostimulation is an effective treatment for refractory epilepsy with few major complications. Seizure-reduction rates among the three therapies were similar during the initial blinded phase with promising long term follow-up studies are for RNS and DBS, however encouraging long term follow up is lacking for VNS.

Heminghyt et al. (2022) conducted a randomized controlled trial evaluating the cognitive impacts of ANT-DBS in the treatment of refractory epilepsy. Eighteen participants were enrolled, ages 18-52 with refractory epilepsy. The first six months were blinded where 8 participants were in the group receiving stimulation, and ten were in the control group. After the initial six months, all participants received stimulation. The participants were assessed via 22 neuropsychological assessments at baseline, at six months, and at one year post implantation. There were no significant group differences in cognitive change between baseline and six months, patients reported fewer symptoms of executive dysfunction in the group who had a full 12 months of stimulation. Patients showing significant improvement in seizure frequency had better performance in a measure of verbal learning. The authors concluded the results indicate that ANT-DBS has limited effects on cognitive functioning, as measured by formal tests after 6- or 12-month stimulation; but may have a positive influence on executive function.

Herrman et al. (2019) conducted a prospective, randomized, double-blind evaluation of the safety and efficacy of DBS for adult patients with focal refractory epilepsy, 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.

**The SANTE Clinical Trial**
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 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 adverse events in the SANTE Trial blinded phase and their relationship to objective neurobehavioral measures, baseline characteristics, quality of life, and long-term neurobehavioral outcome. The neurobehavioral adverse events and neuropsychological data from the SANTE Trial were analyzed. A seven-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 adverse events 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 adverse events than the control group.

- 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).

**National and Specialty Organizations**

**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 (Gummadavelli 2022).

**National Institute for Health and Care Excellence (NICE)** published DBS guidance for patients with refractory epilepsy in August 2020. 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.

## CODING & BILLING INFORMATION

**CPT (Current Procedural Terminology) Codes**

| Code | 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 (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** | Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays |
| **61888** | Revision or removal of cranial neurostimulator pulse generator or receiver |
| **95970** | Electronic analysis of implanted neurostimulator pulse generator/transmitter (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, 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 (Healthcare Common Procedure Coding System) Codes**

| Code | Description |
|---|---|
| **C1767** | Generator, neurostimulator (implantable), non-rechargeable |
| **C1778** | Lead, neurostimulator (implantable) |
| **C1787** | Patient programmer, neurostimulator |
| **C1820** | Generator, neurostimulator (implantable), with rechargeable battery and charging system |
| **C1822** | Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system |
| **L8680** | Implantable neurostimulator electrode, each |
| **L8681** | Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only |
| **L8682** | Implantable neurostimulator radiofrequency receiver |
| **L8683** | Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver |
| **L8685** | Implantable neurostimulator pulse generator, single array, rechargeable, includes extension |
| **L8686** | Implantable neurostimulator pulse generator, single array, non rechargeable, includes extension |
| **L8687** | Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension |
| **L8688** | Implantable neurostimulator pulse generator, dual array, non rechargeable, includes extension |
| **L8689** | External recharging system for battery (internal) for use with implantable neurostimulator, replacement only |
| **L8695** | External recharging system for battery (external) for use with implantable neurostimulator, replacement only |

**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

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|---|---|
| **02/14/2024** | Policy reviewed. No changes to coverage criteria, updated overview, and summary of medical evidence. |
| **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. IRO Peer reviewed in Jan 2023, by a practicing physician board certified in Neurological Surgery. |
| **02/09/2022** | Policy reviewed, no changes to coverage, updated references. |
| **02/08/2021** | Policy reviewed, no changes to coverage, updated references. |
| **04/23/2020** | Policy reviewed, no changes to coverage, updated references. |
| **03/11/2019** | New policy. IRO Peer Review. Policy reviewed on November 11, 2019, by a practicing, board-certified physician in Neurology. |

## REFERENCES

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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.*