LOUISIANA BLUE

# Deep Brain Stimulation

**Policy # 00024**
Original Effective Date: 08/25/2005
Current Effective Date: 12/01/2025

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Note: Responsive Neurostimulation for the Treatment of Refractory Focal Epilepsy is addressed separately in medical policy 00674.*

*Note: Vagus Nerve Stimulation is addressed separately in medical policy 00134.*

## When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider unilateral deep brain stimulation (DBS) of the thalamus in individuals with disabling, medically unresponsive tremor due to essential tremor (ET) or Parkinson's disease (PD) to be **eligible for coverage.****

Based on review of available data, the Company may consider bilateral deep brain stimulation (DBS) of the thalamus in individuals with disabling, medically unresponsive tremor in both upper limbs due to essential tremor (ET) or Parkinson's disease (PD) to be **eligible for coverage.****

Based on review of available data, the Company may consider unilateral or bilateral deep brain stimulation (DBS) of the globus pallidus or subthalamic nucleus when patient selection criteria are met to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility will be considered for unilateral or bilateral deep brain stimulation (DBS) of the globus pallidus or subthalamic nucleus when all of the following criteria are met:

- Parkinson disease and ALL of the following:
  - A good response to levodopa; AND
  - Motor complications not controlled by pharmacologic therapy; AND
  - One of the following:
    - A minimum score of 30 points on the motor portion of the Unified Parkinson Disease Rating Scale when the patient has been without medication for approximately 12 hours OR
    - Parkinson disease for at least 4 years

- Individuals older than 7 years with chronic, intractable (drug-refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis).

# When Services Are Considered Not Medically Necessary

Based on review of available data, the Company may consider deep brain stimulation (DBS) to be **not medically necessary**** when the following contraindications are present:

- Individuals who are not good surgical risks because of unstable medical problems or because of the presence of a cardiac pacemaker; or
- Individuals who have medical conditions that require repeated magnetic resonance imaging (MRI); or
- Individuals who have dementia that may interfere with the ability to cooperate; or
- Individuals who have had botulinum toxin injections within the last six months.

# When Services Are Considered Investigational

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers adaptive deep brain stimulation for Parkinson disease is considered **investigational*** (see Patient Selection Criteria).

Based on review of available data, the Company considers deep brain stimulation for other movement disorders, including but not limited to tardive dyskinesia and post-traumatic dyskinesia to be **investigational.***

Based on review of available data, the Company considers deep brain stimulation for the treatment of chronic cluster headaches to be **investigational.***

Based on review of available data, the Company considers deep brain stimulation for the treatment of other psychiatric or neurologic disorders, including but not limited to epilepsy, Tourette syndrome, depression, obsessive-compulsive disorder, anorexia nervosa, alcohol addiction, Alzheimer disease, multiple sclerosis tremor, and chronic pain, to be **investigational.***

# Policy Guidelines

Disabling, medically unresponsive tremor defined as:

- Tremor causing significant limitation in daily activities; and
- Inadequate control by maximal dosage of medication for at least three months before implant.

Contraindications to deep brain stimulation include:

- individuals who are not good surgical risks because of unstable medical problems or because of the presence of a cardiac pacemaker
- individuals who have medical conditions that require repeated magnetic resonance imaging
- individuals who have dementia that may interfere with the ability to cooperate
- individuals who have had botulinum toxin injections within the last 6 months

Accessory or software adjustments for individuals with a pre-existing DBS will be considered on a case by case basis. Parkinson disease is a complex condition and might entail a complex system of care particularly when the disease has advanced. Adaptive DBS (aDBS) is a closed-loop system incorporating feedback from brain signals to dynamically adjust stimulation parameters. It is a more personalized approach to treatment of advanced disease and holds promise for reducing stimulation duration and energy consumption while treating motor related issues such as dyskinesia. The FDA submission for aDBS by Medtronic was as an optional programming feature for Parkinson's Disease in existing devices. It was not studied in bilaterally implanted neurostimulators, and the labeling instructs not to use aDBS with more than one implanted neurostimulator.

# Background/Overview

**Deep Brain Stimulation**

Deep brain stimulation involves the stereotactic placement of an electrode into the brain (ie, hypothalamus, thalamus, globus pallidus, or subthalamic nucleus). The electrode is initially attached to a temporary transcutaneous cable for short-term stimulation to validate treatment effectiveness. Several days later, the patient returns for permanent subcutaneous surgical implantation of the cable and a radiofrequency-coupled or battery-powered programmable stimulator. The electrode is typically implanted unilaterally on the side corresponding to the most severe symptoms. However, the use of bilateral stimulation using 2 electrode arrays has also been investigated in patients with bilateral, severe symptoms. After implantation, noninvasive programming of the neurostimulator can be adjusted to the patient's symptoms. This feature may be important for patients with Parkinson disease, whose disease may progress over time, requiring different neurostimulation parameters. Setting the optimal neurostimulation parameters may involve the balance between optimal symptom control and appearance of adverse effects of neurostimulation, such as dysarthria, disequilibrium, or involuntary movements.

# FDA or Other Governmental Regulatory Approval

**U.S. Food and Drug Administration (FDA)**

In 1997, the Activa®‡ Tremor Control System (Medtronic) was approved by the U.S. Food and Drug Administration (FDA) through the pre-market approval process for deep brain stimulation. The Activa Tremor Control System consists of an implantable neurostimulator, a deep brain stimulator lead, an extension that connects the lead to the power source, a console programmer, a software

cartridge to set electrical parameters for stimulation, and a patient control magnet, which allows the patient to turn the neurostimulator on and off, or change between high and low settings.

The FDA-labeled indications for Activa were originally limited to unilateral implantation for the treatment of tremor, but the indications have evolved over time. In 2002, the FDA labeled indications were expanded to include bilateral implantation as a treatment to decrease the symptoms of advanced Parkinson disease not controlled by medication. In 2003, the labeled indications were further expanded to include "…unilateral or bilateral stimulation of the internal globus pallidus or subthalamic nucleus to aid in the management of chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis) in patients 7 years of age or above." In 2018, the deep brain stimulation system received an expanded indication as an adjunctive therapy for epilepsy (P960009-S219). Other deep brain stimulation systems are described in Table 1.

**Table 1. Deep Brain Stimulation Systems**

| System | Manufacturer | FDA Product Code | PMA or HDE | Approval Date | Indications |
|---|---|---|---|---|---|
| Activa®‡ Deep Brain Stimulation Therapy System | Medtronic | MBX | P96009 | 1997 | Unilateral or bilateral stimulation of the internal globus pallidus or subthalamic nucleus for symptoms of Parkinson disease or primary dystonia |
| Reclaim®‡ DBS Therapy for Obsessive Compulsive Disorder | Medtronic | | H050003 | 2009 | Bilateral stimulation of the anterior limb of the internal capsule for severe obsessive-compulsive disorder |
| Brio Neurostimulation System | St. Jude Medical | NHL | P140009 | 2015 | Parkinsonian tremor (subthalamic nucleus) and essential tremor (thalamus) |
| Infinity DBS | Abbott Medical/St. Jude Medical | PJS | P140009 | 2016 | Parkinsonian tremor |

| | | | | | |
|---|---|---|---|---|---|
| Vercise DBS System | Boston Scientific | NHL | P150031 | 2017 | Moderate-to-advanced levodopa-responsive PD inadequately controlled with medication alone |
| Medtronic DBS System for Epilepsy | Medtronic | MBX | P960009-S219 | 2018 | Expanded indication for epilepsy with bilateral stimulation of the anterior nucleus of the thalamus |
| Percept PC Deep Brain Stimulation | Medtronic | MHY | P960009-S | 2020 | Records brain signals while delivering therapy for PD or primary dystonia |
| Vercise Genus DBS System | Boston Scientific | NHL | P150031-S034 | 2021 | Stimulation of the subthalamic nucleus and globus pallidus for PD |
| SenSight Directional Lead System | Medtronic | MHY | P960009 | 2021 | Unilateral or bilateral stimulation for PD, tremor, dystonia, and epilepsy |
| BrainSense™‡ Adaptive Deep Brain Stimulation | Medtronic | MHY | P960009 | 2025 | Automatically adjusted therapeutic stimulation to maximize reduction of PD symptoms |

DBS: deep brain stimulation; HDE: humanitarian device exemption; PD: Parkinson disease; PMA: premarket approval

# Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

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**Description**
Deep brain stimulation involves the stereotactic placement of an electrode into a central nervous system nucleus (eg, hypothalamus, thalamus, globus pallidus, subthalamic nucleus). Deep brain stimulation is used as an alternative to permanent neuroablative procedures for control of essential tremor and Parkinson disease. Deep brain stimulation is also being evaluated for the treatment of a variety of other neurologic and psychiatric disorders.

**Summary of Evidence**
For individuals who have essential tremor or tremor in Parkinson disease who receive deep brain stimulation of the thalamus, the evidence includes a systematic review and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The systematic review (a TEC Assessment) concluded that there was sufficient evidence that deep brain stimulation of the thalamus results in clinically significant tremor suppression and that outcomes after deep brain stimulation were at least as good as thalamotomy. Subsequent studies reporting long-term follow-up have supported the conclusions of the TEC Assessment and found that tremors were effectively controlled 5 to 6 years after deep brain stimulation. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have symptoms (eg, speech, motor fluctuations) associated with Parkinson disease (advanced or >4 years in duration with early motor symptoms) who receive deep brain stimulation of the globus pallidus interna or subthalamic nucleus, the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. One of the systematic reviews (a TEC Assessment) concluded that studies evaluating deep brain stimulation of the globus pallidus interna or subthalamic nucleus have consistently demonstrated clinically significant improvements in outcomes (eg, neurologic function). Other systematic reviews have also found significantly better outcomes after deep brain stimulation than after a control intervention. An RCT in patients with levodopa-responsive Parkinson disease of at least 4 years in duration and uncontrolled motor symptoms found that quality of life at 2 years was significantly higher when deep brain stimulation was provided in addition to medical therapy. Meta-analyses of RCTs comparing deep brain stimulation of the globus pallidus interna with deep brain stimulation of the subthalamic nucleus have reported mixed findings and have not shown that 1 type of stimulation is superior to the other. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with symptoms associated with Parkinson disease who receive adaptive deep brain stimulation of the globus pallidus interna or subthalamic nucleus, the evidence includes one RCT. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. There is currently one ongoing RCT assessing the feasibility and efficacy of adaptive deep brain stimulation (aDBS) for control of Parkinson disease symptoms. One RCT assessed the feasibility and efficacy of adaptive deep brain stimulation for control of Parkinson disease

symptoms. The primary efficacy outcome measured "On" time without dyskinesia, with success rates of 78.9% for single-threshold aDBS and 91% for dual-threshold aDBS. Safety analysis showed that overall 78.8% of patients experienced adverse events, 56.5% had device-related events, and 17.6% had serious adverse events, including one participant with 2 severe device-related injuries. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have primary dystonia who receive deep brain stimulation of the globus pallidus interna or subthalamic nucleus, the evidence includes systematic reviews, RCTs, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A pooled analysis of 24 studies, mainly uncontrolled, found improvements in motor scores and disability scores after 6 months and at last follow-up (mean, 32 months). Both double-blind RCTs found that severity scores improved more after active than after sham stimulation. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have tardive dyskinesia or tardive dystonia who receive deep brain stimulation, the evidence includes an RCT and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The RCT did not report statistically significant improvement in the dystonia severity outcomes or the secondary outcomes related to disability and quality of life, but these may have been underpowered. Additional studies, especially RCTs or other controlled studies, are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have epilepsy who receive deep brain stimulation, the evidence includes systematic reviews, RCTs, and many observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Two RCTs with more than 15 patients were identified. The first RCT (N=110) evaluated anterior thalamic nucleus deep brain stimulation and reported that deep brain stimulation had a positive impact on seizure frequency during some parts of the blinded trial phase, but not others, and a substantial number of adverse events (in >30% of patients). There were no differences between groups in 50% responder rates, Liverpool Seizure Severity Scale, or Quality of Life in Epilepsy scores. A 7-year open-label follow-up of the RCT included 66% of implanted patients; reasons for missing data were primarily related to adverse events or dissatisfaction with the device. Reduction in seizure frequency continued to improve during follow-up among the patients who continued follow-up. The second RCT (N=16) showed a benefit with deep brain stimulation. Many observational studies reported fewer seizures compared with baseline, however, without control groups, interpretation of these results is limited. Additional trials are required to determine the impact of deep brain stimulation on patient outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have Tourette syndrome who receive deep brain stimulation, the evidence includes observational studies, RCTs, and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Two RCTs with 15 or more patients have been reported. One RCT found differences in severity of Tourette syndrome for active versus sham at 3 months while the other RCT did not. Neither study demonstrated improvements in comorbid symptoms of obsessive-compulsive disorder or depression. Both studies reported high rates of serious adverse events. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have cluster headaches or facial pain who receive deep brain stimulation, the evidence includes a systematic review, randomized crossover study, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The systematic review included an individual patient data meta-analysis of 34 patients, showing a significant reduction in pain intensity at 3 months following deep brain stimulation for chronic facial pain; data for follow-up beyond 3 months were not eligible for statistical analysis. In an RCT of 11 patients with severe, refractory, chronic cluster headache , the between-group difference in response rates did not differ significantly between active and sham stimulation phases. Additional RCTs or controlled studies are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have treatment-resistant depression who receive deep brain stimulation, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A number of case series and several prospective controlled trials evaluating deep brain stimulation have been published. Two RCTs of deep brain stimulation in the subgenual cingulate cortex and ventral striatum/ventral capsule were terminated for futility. Another RCT of stimulation of the same brain area (ventral striatum/ventral capsule) did not find a statistically significant difference between groups in the primary outcome (clinical response), and adverse psychiatric events occurred more frequently in the treatment group than in the control group. More recently, a controlled crossover trial randomized patients to sham or active stimulation of the anterior limb of the internal capsule after a year of open-label stimulation. There was a greater reduction in symptom scores after active stimulation, but only in patients who were responders in the open-label phase. Stimulation of the subcallosal (subgenual) cingulate was evaluated in a 2019 sham-controlled within-subject study that found prolonged response in 50% of patients and remission in 30% of patients with treatment-resistant depression. Deep brain stimulation for patients with major depressive disorder who have failed all other treatment options is an active area of research, but the brain regions that might prove to be effective for treatment-resistant depression have yet to be established. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have obsessive-compulsive disorder who receive deep brain stimulation, the evidence includes meta-analyses of RCTs. Relevant outcomes are symptoms, functional outcomes,

quality of life, and treatment-related morbidity. Among the RCTs on deep brain stimulation for obsessive-compulsive disorder included in meta-analyses, only 1 has reported an outcome of clinical interest (therapeutic response rate), and that trial did not find a statistically significant benefit for deep brain stimulation compared with sham treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have other neurologic or psychiatric disorders who receive deep brain stimulation, the evidence includes a number of nonrandomized studies or RCTs in patients with multiple sclerosis, chronic pain, or alcohol use disorder. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. One RCT with 10 multiple sclerosis patients, 2 RCTs in patients with chronic pain, and 1 RCT in patients with treatment-refractory alcohol use disorder is insufficient evidence on which to draw conclusions about the efficacy of deep brain stimulation in these populations. Additional trials are required. For individuals who have anorexia nervosa, Alzheimer disease, Huntington disease, or chronic pain who receive deep brain stimulation, the evidence includes case series; RCTs are needed to evaluate the efficacy of deep brain stimulation for these conditions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

# Supplemental Information

### Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

### 2014 Input

In response to requests, input was received from 2 academic medical centers and 2 physician specialty societies while this policy was under review in 2014. Input supported the use of bilateral deep brain stimulation in individuals with medically unresponsive tremor in both limbs.

### Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

**American Academy of Neurology**
**Essential Tremor**
In 2011, the American Academy of Neurology (AAN) updated its guidelines on the treatment of essential tremor, which were reaffirmed in 2022. This update did not change the conclusions and recommendations of the AAN (2005) practice parameters on deep brain stimulation for essential tumor. The guidelines stated that bilateral deep brain stimulation of the thalamic nucleus may be used to treat medically refractory limb tremor in both upper limbs (level C, possibly effective) but that there were insufficient data on the risk/benefit ratio of bilateral versus unilateral deep brain stimulation in the treatment of limb tremor. There was insufficient evidence to make recommendations on the use of thalamic deep brain stimulation for head or voice tremor (level U, treatment is unproven).

**Parkinson Disease**
In 2018, the AAN affirmed the guideline developed by the Congress of Neurological Surgeons (see Table 2).

**Tourette Syndrome**
Guidelines from AAN (2019, reaffirmed 2022) provide recommendations on the assessment for and use of deep brain stimulation in adults with severe, treatment-refractory tics. The AAN notes that patients with severe Tourette syndrome resistant to medical and behavioral therapy may benefit from deep brain stimulation, but there is no consensus on the optimal brain target. Brain regions that have been stimulated in patients with Tourette syndrome include the centromedian thalamus, the globus pallidus internus (ventral and dorsal), the globus pallidus externus, the subthalamic nucleus, and the ventral striatum/ventral capsular nucleus accumbens region. The AAN concludes that deep brain stimulation of the anteromedial globus pallidus is possibly more likely than sham stimulation to reduce tic severity.

**American Society for Stereotactic and Functional Neurosurgery**
**Obsessive-Compulsive Disorder**
In 2021, the American Society for Stereotactic and Functional Neurosurgery and the Congress of Neurological Surgeons updated their 2014 guidelines on deep brain stimulation for obsessive-compulsive disorder. The document concluded that there was a single level I study supporting the use of bilateral subthalamic nucleus deep brain stimulation for medically refractory obsessive-compulsive disorder and a single level II study supporting bilateral nucleus accumbens or bed nucleus of stria terminalis deep brain stimulation for medically refractory obsessive-compulsive disorder. It also concluded that the evidence on unilateral deep brain stimulation was insufficient.

**Refractory Epilepsy**
In 2022, the American Society for Stereotactic and Functional Neurosurgery published a position statement on deep brain stimulation for medication-refractory epilepsy. Indications for deep brain stimulation include confirmed diagnosis of epilepsy (focal onset seizures with or without

generalization), failure to achieve seizure control after 2 or more appropriately dosed seizure medications, seizures with localized onset in a region that cannot be resected or for which surgical resection has failed, or focal-onset seizures with a nonlocalized or unclear region of onset.

**Congress of Neurologic Surgeons**
**Parkinson Disease**
In 2018, evidence-based guidelines from the Congress of Neurologic Surgeons, affirmed by the AAN, compared the efficacy of bi-lateral deep brain stimulation of the subthalamic nucleus and globus pallidus internus for the treatment of patients with Parkinson disease.

**Table 2. Recommendations of the Congress of Neurologic Surgeons for DBS for Parkinson Disease**

| Goal | Most Effective Area of Stimulation (subthalamic nucleus or globus pallidus internus) | Level of Evidence |
|---|---|---|
| Improving motor symptoms | subthalamic nucleus or globus pallidus internus are similarly effective | I |
| Reduction of dopaminergic medication | subthalamic nucleus | I |
| Treatment of "on" medication dyskinesias | globus pallidus internus if reduction of medication is not anticipated | I |
| Quality of life | no evidence to recommend one over the other | I |
| Lessen impact of DBS on cognitive decline | globus pallidus internus | I |
| Reduce risk of depression | globus pallidus internus | I |
| Reduce adverse effects | insufficient evidence to recommend one over the other | Insufficient |

DBS: Deep brain stimulation

**National Institute for Health and Care Excellence**
The United Kingdom's NICE has published guidance documents on deep brain stimulation, as discussed in the following subsections.

**Tremor and Dystonia**
In 2006, NICE made the same statements about use of deep brain stimulation for treatment of both tremor and dystonia. Unilateral and bilateral stimulation of structures responsible for modifying movements, such as the thalamus, globus pallidus, and the subthalamic nucleus, which interact

functionally with the substantia nigra, are included in both guidance statements. The guidance stated: "Current evidence on the safety and efficacy of deep brain stimulation for tremor and dystonia (excluding Parkinson disease) appears adequate to support the use of this procedure."

**Refractory Chronic Pain Syndromes (Excluding Headache)**
In 2011, guidance from NICE indicated there is evidence that deep brain stimulation for refractory chronic pain (excluding headache) is associated with serious risks. However, the procedure is "efficacious in some patients" refractory to other treatments." Patients should be informed that deep brain stimulation may not control their chronic pain symptoms and that possible risks associated with this procedure include the small risk of death.

**Intractable Trigeminal Autonomic Cephalalgias**
In 2011, guidance from NICE indicated that the evidence on the efficacy of deep brain stimulation for intractable trigeminal autonomic cephalalgias (eg, cluster headaches) was "limited and inconsistent, and the evidence on safety shows that there were serious but well-known adverse effects."

**Refractory Epilepsy**
In 2020, guidance from NICE indicated that the evidence on the efficacy and safety of deep brain stimulation for refractory epilepsy (for anterior thalamic targets) was limited in both quantity and quality, and "this procedure should only be used with special arrangements for clinical governance, consent, and audit or research". For targets other than the anterior thalamus, NICE recommends that "this procedure should only be used in the context of research".

**Parkinson Disease**
In 2003, NICE stated that the evidence on the safety and efficacy of deep brain stimulation for treatment of Parkinson disease "appears adequate to support the use of the procedure." The guidance noted that deep brain stimulation should only be offered when Parkinson disease is refractory to best medical treatment.

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

**Medicare National Coverage**
Effective for services furnished in April 2003, Medicare covers unilateral or bilateral thalamic ventralis intermedius nucleus deep brain stimulation for the treatment of essential tumor and/or parkinsonian tremor and unilateral or bilateral subthalamic nucleus or globus pallidus interna deep brain stimulation for the treatment of Parkinson disease when the following conditions are met:

1. Devices must be approved by the Food and Drug Administration (FDA) for "deep brain stimulation or devices used in accordance with FDA-approved protocols governing Category B Investigational Device Exemption (IDE) deep brain stimulation clinical trials."

2. For thalamic ventralis intermedius nucleus deep brain stimulation, patients must meet all of the following criteria:
    a. "Diagnosis of ET [essential t remor] based on postural or kinetic tremors of hand(s) without other neurologic signs, or diagnosis of idiopathic Parkinson disease (presence of at least 2 cardinal PD [Parkinson disease] features (tremor, rigidity or bradykinesia)) which is of a tremor-dominant form.
    b. Marked disabling tremor of at least level 3 or 4 on the Fahn-Tolosa-Marin Clinical Tremor Rating Scale (or equivalent scale) in the extremity intended for treatment, causing significant limitation in daily activities despite optimal medical therapy.
    c. Willingness and ability to cooperate during conscious operative procedure, as well as during postsurgical evaluations, adjustments of medications and stimulator settings."
3. For subthalamic nucleus or globus pallidus interna deep brain stimulation, patients must meet all of the following criteria:
    a. "Diagnosis of PD based on the presence of at least 2 cardinal Parkinson disease features (tremor, rigidity or bradykinesia).
    b. Advanced idiopathic PD as determined by the use of Hoehn and Yahr stage or Unified Parkinson's Disease Rating Scale part III motor subscale.
    c. L-dopa responsive with clearly defined 'on' periods.
    d. Persistent disabling Parkinson's symptoms or drug side effects (eg, dyskinesias, motor fluctuations, or disabling 'off' periods) despite optimal medical therapy.
    e. Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings."

Deep brain stimulation is not covered for essential tumor or Parkinson disease patients with any of the following:

1. "Non-idiopathic Parkinson's disease or 'Parkinson's Plus' syndromes.
2. Cognitive impairment, dementia or depression, which would be worsened by or would interfere with the patient's ability to benefit from DBS [deep brain stimulation].
3. Current psychosis, alcohol abuse or other drug abuse.

Structural lesions such as basal ganglionic stroke, tumor or vascular malformation as etiology of the movement disorder.

Previous movement disorder surgery within the affected basal ganglion.

Significant medical, surgical, neurologic or orthopedic co-morbidities contraindicating DBS [deep brain stimulation] surgery or stimulation."

**Ongoing and Unpublished Clinical Trials**
Some currently unpublished trials that might influence this review are listed in Table 3. Included are randomized controlled trials with at least 40 participants, excluding trials on deep brain stimulation for Parkinson disease.

**Table 3. Summary of Key Trials**

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| *Ongoing* | | | |
| **Epilepsy** | | | |
| NCT04164056 | Hippocampal and Thalamic deep brain stimulation for Bilateral Temporal Lobe Epilepsy | 80 | Sep 2024 |
| NCT03900468[a] | Medtronic Deep Brain Stimulation Therapy for Epilepsy Post-Approval Study (EPAS) | 140 | Mar 2028 |
| NCT06248333 | Subthalamic Nucleus Electrical Stimulation for Drug-resistant Focal Motor Epilepsy (STEM) | 33 | Jan 2026 |
| NCT06364085 | EPI-BOOST: Enhancing Epilepsy Management With Precision Deep Brain Stimulation | 40 | Jun 2026 |
| **Huntington's Disease** | | | |
| NCT04244513[a] | Deep Brain Stimulation Treatment for Chorea in Huntington's Disease | 40 | Dec 2023 |
| **Obsessive-Compulsive Disorder** | | | |
| NCT02773082[a] | Reclaim Deep Brain Stimulation Therapy for Obsessive-Compulsive Disorder (OCD) | 50 | Jan 2030 |
| NCT02844049 | European Study of Quality of Life in Resistant OCD Patients Treated by subthalamic nucleus deep brain stimulation | 60 | Apr 2027 |

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| NCT05995951 | Deep Brain Stimulation Surgery for the Treatment of Refractory Obsessive-Compulsive Disorder | 10 | Sept 2025 |
| **Treatment Resistant Depression** | | | |
| NCT03653858[a] | Controlled Randomized Clinical Trial to Assess Efficacy of Deep Brain Stimulation of the slMFB in Patients With Treatment Resistant Major Depression (FORSEEIII) | 47 | Jun 2025 |
| NCT06096207 | DBS for Depression | 20 | Oct 2038 |
| **Alzheimer Disease** | | | |
| NCT03622905 | ADvance II Study: DBS-f in Patients With Mild Alzheimer's Disease | 74 | Feb 2024 |
| NCT05882344 | Deep Brain Stimulation for Alzheimer's | 2 | Oct 2028 |
| NCT05762926 | Non-invasive Brain Stimulation by Transcranial Pulse Stimulation as a Coadjunctive Treatment in Alzheimer's Disease | 50 | May 2024 |
| *Unpublished* | | | |
| NCT02076698 | Deep Brain Stimulation of the Anterior Nucleus of the Thalamus in Epilepsy | 62 | Nov 2021 |
| NCT04181229 | Deep Brain Stimulation After Failed Vagal Nerve Stimulation for the Treatment of Drug-Resistant Epilepsy in Children | 25 | Mar 2023 |

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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# Policy History

Original Effective Date: 08/25/2005
Current Effective Date: 12/01/2025

| | |
|---|---|
| 03/21/2002 | Medical Policy Committee review |
| 03/25/2002 | Managed Care Advisory Council approval |
| 06/24/2002 | Format revision. No substance change to policy. |
| 08/03/2004 | Medical Director review |

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|---|---|
| 08/17/2004 | Medical Policy Committee review |
| 08/30/2004 | Managed Care Advisory Council approval |
| 07/14/2005 | Medical Director review |
| 07/19/2005 | Medical Policy Committee review. Clinical criteria revision. Coverage eligibility changes. Added investigational statement for DBS for cluster headaches. |
| 08/24/2005 | Managed Care Advisory Council approval |
| 06/07/2006 | Medical Director review |
| 06/21/2006 | Medical Policy Committee approval. Format revisions, FDA/Governmental, Rationale/Source. Coverage eligibility unchanged. |
| 08/01/2007 | Medical Director review |
| 08/15/2007 | Medical Policy Committee approval. No change to coverage eligibility. |
| 08/06/2008 | Medical Director review |
| 08/20/2008 | Medical Policy Committee approval. Tardive dyskinesia, Tourette syndrome, depression and epilepsy were added to the list of investigational indications. |
| 08/06/2009 | Medical Policy Committee approval |
| 08/26/2009 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 07/01/2010 | Medical Policy Committee approval |
| 07/21/2010 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 07/07/2011 | Medical Policy Committee approval |
| 07/20/2011 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 06/28/2012 | Medical Policy Committee approval |
| 07/27/2012 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 02/04/2013 | Coding Updated |
| 06/27/2013 | Medical Policy Committee approval |
| 07/17/2013 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 07/10/2014 | Medical Policy Committee approval |
| 07/16/2014 | Medical Policy Implementation Committee approval. Added anorexia nervosa, alcohol addiction, and chronic pain as investigational indications |
| 01/01/2015 | Coding Updated |
| 08/03/2015 | Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed. |
| 09/03/2015 | Medical Policy Committee approval |
| 09/23/2015 | Medical Policy Implementation Committee approval. Added eligibility statement for bilateral DBS of thalamus for bilateral tremors and added Alzheimer disease to list of investigational indications |
| 01/01/2016 | Coding update |

Deep Brain Stimulation

Policy # 00024
Original Effective Date: 08/25/2005
Current Effective Date: 12/01/2025

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|---|---|
| 09/08/2016 | Medical Policy Committee approval |
| 09/21/2016 | Medical Policy Implementation Committee approval. Added "upper" to coverage statement for bilateral DBS. |
| 01/01/2017 | Coding update: Removing ICD-9 Diagnosis Codes |
| 09/07/2017 | Medical Policy Committee approval |
| 09/20/2017 | Medical Policy Implementation Committee approval. In medically necessary statement on unilateral or bilateral deep brain stimulation of the globus pallidus or subthalamic nucleus, "OR Parkinson disease for at least 4 years" added to medically necessary criteria for use in Parkinson disease. |
| 09/06/2018 | Medical Policy Committee approval |
| 09/19/2018 | Medical Policy Implementation Committee approval. No change to coverage. |
| 09/05/2019 | Medical Policy Committee approval |
| 09/11/2019 | Medical Policy Implementation Committee approval. No change to coverage. |
| 09/03/2020 | Medical Policy Committee approval |
| 09/09/2020 | Medical Policy Implementation Committee approval. No change to coverage. |
| 12/11/2020 | Coding update |
| 09/02/2021 | Medical Policy Committee approval |
| 09/08/2021 | Medical Policy Implementation Committee approval. No change to coverage. |
| 09/01/2022 | Medical Policy Committee approval |
| 09/14/2022 | Medical Policy Implementation Committee approval. No change to coverage. |
| 09/07/2023 | Medical Policy Committee approval |
| 09/13/2023 | Medical Policy Implementation Committee approval. No change to coverage. |
| 09/05/2024 | Medical Policy Committee approval |
| 09/11/2024 | Medical Policy Implementation Committee approval. No change to coverage. |
| 09/04/2025 | Medical Policy Committee review |
| 09/10/2025 | Medical Policy Implementation Committee approval. Added investigational policy statement for adaptive deep brain stimulation in Parkinson disease. |

Next Scheduled Review Date: 09/2026

# Coding

*The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

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Deep Brain Stimulation

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

| Code Type | Code |
|---|---|
| CPT | 61850, 61860, 61863, 61864, 61867, 61868, 61880, 61885, 61886, 95970, 95983, 95984 |
| HCPCS | C1816, C1820, C1822, C1883, L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688, L8689<br>Add codes effective 12/01/2025: C1767, L8679<br>Delete codes effective 12/01/2025: C1823, L8684 |
| ICD-10 Diagnosis | All related diagnoses |

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.



**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

**NOTICE:** Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.