



MEDICAL COVERAGE POLICY

SERVICE: Seizure Disorders: Invasive Treatments (Epilepsy Surgery)

Policy Number: 013

Effective Date: 10/01/2024

Last Review: 09/09/2024

Next Review: 09/09/2025

Important note: Unless otherwise indicated, medical policies will apply to all lines of business.

Medical necessity as defined by this policy does not ensure the benefit is covered. This medical policy does not replace existing federal or state rules and regulations for the applicable service or supply. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan documents. See the member plan specific benefit plan document for a complete description of plan benefits, exclusions, limitations, and conditions of coverage. In the event of a discrepancy, the plan document always supersedes the information in this policy.

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PRIOR AUTHORIZATION: Required.

POLICY: Please review the plan's EOC (Evidence of Coverage) or Summary Plan Description (SPD) for coverage details.

Note: Unless otherwise indicated (see below), this policy will apply to all lines of business.

For Medicare plans, please refer to appropriate Medicare NCD (National Coverage Determination) or LCD (Local Coverage Determination). Medicare NCD or LCD specific InterQual criteria may be used when available. If there are no applicable NCD or LCD criteria, use the criteria set forth below.

For Medicaid plans, please confirm coverage as outlined in the [Texas Medicaid Provider Procedures Manual | TMHP](#) (TMPPM). If there are no applicable criteria to guide medical necessity decision making in the TMPPM, use the criteria set forth below.

BSWHP may consider surgical intervention by cerebral hemispherectomy, corpus callosotomy, and temporal lobectomy medically necessary when **ALL** of the following criteria are met:

1. Member is at least 18 years old **OR** under 18 years of age with a suitable pediatric seizure diagnosis (e.g., unilateral multi-focal epilepsy associated with infantile hemiplegia as seen in hemimegalencephaly and Sturge-Weber disease); **AND**
2. Non-epileptic events or conditions such as cardiogenic syncope and psychogenic seizures have been ruled out; **AND**
3. The diagnosis of epilepsy has been documented, and the epileptic seizure type and the epileptic syndrome has been clearly defined; **AND**
4. Seizures occur at a frequency that interferes with members' daily living and threatens their well-being; **AND**
5. There has been an adequate trial of drug therapy, with at least two appropriate antiepileptic medications at therapeutic levels, and with member compliance **OR** member has failed at least two drug therapies due to medication toxicity / adverse effects; **AND**
6. The individual is not a candidate for **OR** has failed invasive neurostimulation therapy.



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BSWHP may consider laser interstitial thermal therapy (LITT) and magnetic resonance-guided laser interstitial thermal therapy (e.g. NeuroBlate and Visualase Thermal Therapy System) medically necessary when ALL of the above surgical intervention criteria are met AND the following criteria are met:

1. There are LITT accessible well-defined epileptogenic foci; **AND**
2. LITT is determined to be the best treatment option by a multidisciplinary physician team of at least two specialties (e.g., neurosurgery, neurology)

BSWHP may consider bilateral stimulation of the anterior nucleus of the thalamus (e.g., Medtronic DBS System for Epilepsy) medically necessary when ALL of the following criteria are met:

1. Member is at least 18 years old; **AND**
2. The diagnosis of partial onset seizure with or without secondary generalization to tonic-clonic activity is documented; **AND**
3. There has been an adequate trial of drug therapy, with at least three appropriate antiepileptic medications at therapeutic levels, and with member compliance **OR** member has failed at least three drug therapies due to medication toxicity / adverse effects; **AND**
4. Seizures occur at a frequency (average of at least 6 per month over the previous 3-month period, with no more than 30 days between seizures) that interferes with members' daily living and threatens their well-being.

BSWHP may consider responsive neurostimulation (RNS) (e.g., the NeuroPace RNS System) medically necessary for adults with intractable focal aware seizures (partial onset seizures) when the following criteria are met:

1. Member is at least 18 years old; **AND**
2. Non-epileptic events or conditions such as cardiogenic syncope and psychogenic seizures have been ruled out; **AND**
3. The diagnosis of epilepsy has been documented, and the epileptic seizure type and the epileptic syndrome has been clearly defined; **AND**
4. Seizures (e.g., motor partial seizures, complex partial and/or secondarily generalized seizures) occur at a frequency (average of 3 per month over the previous 3-month period) that interferes with members' daily living and threatens their well-being; **AND**
5. There has been an adequate trial of drug therapy, with at least two appropriate antiepileptic medications at therapeutic levels, and with member compliance: **AND**
6. The member has no more than two epileptogenic regions; **AND**
7. Member is not a candidate for resective epilepsy surgery because epileptic focus is near regions of concern e.g., language or memory; **AND**
8. Member has ability, or has the necessary assistance, to properly operate the device; **AND**
9. Member has none of the following contraindications:
 - Three or more specific seizure foci



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- Presence of generalized epilepsy
- Presence of rapidly progressive neurologic disorder
- Presence of other implanted medical devices that deliver electrical energy to the brain

RNS is considered experimental, investigational, or unproven for all other indications.

Vagus Nerve Stimulation (non-responsive or open loop)

1. **For Medicare plans**, please review using criteria set forth in [NCD 160.18 Vagus Nerve Stimulation \(VNS\).18](#). Medicare NCD or LCD specific InterQual criteria may be used when available. If there are no applicable NCD or LCD criteria, use the criteria set forth below.
2. **For all other plans, BSWHP may consider vagus nerve stimulation (non-responsive or open loop)** medically necessary for epilepsy when the following criteria are met:
 - a. There has been an adequate trial of drug therapy, with at least two appropriate antiepileptic medications at therapeutic levels, and with member compliance **OR** member has failed at least two drug therapies due to medication toxicity / adverse effects; **AND**
 - b. Member does not have contraindication to vagus nerve stimulation (e.g., history of left or bilateral cervical vagotomy).

Responsive (closed loop) and transcutaneous (non-implantable) vagus nerve stimulation devices are unproven and not medically necessary due to insufficient evidence of efficacy.

Cerebral hemispherectomy, corpus callosotomy, and temporal lobectomy are considered experimental and investigational when selection criteria are not met.

Cerebellar stimulation or deep brain stimulation for members with intractable seizures are considered experimental and investigational because their effectiveness for this indication has not been established.

Localized neocortical resections are considered experimental and investigational for uncontrolled complex partial seizures because its effectiveness has not been established.

Hippocampal electrical stimulation for the treatment of mesial-temporal lobe epilepsy is considered experimental and investigational because its effectiveness has not been established.

The use of stereotactic radiosurgery including radiofrequency amygdalohippocampectomy for medial temporal lobe epilepsy and epilepsy arising in other functional cortical regions is considered experimental and investigational because its effectiveness has not been established.

High-Frequency Oscillations in epilepsy surgery planning is considered experimental and investigational because its effectiveness has not been established.

BSWHP requires prior authorization for all procedures as well as for planning procedures if



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epilepsy surgery is under consideration. Only evidence-based services as outlined in this policy will be authorized.

BACKGROUND:

Patients who have intractable epileptic seizures despite adequate treatment with appropriate antiepileptic drugs, can be offered relief with neurostimulators or surgery. The goal of invasive treatments for intractable seizures is to decrease the frequency of seizures and improve quality of life.

Deep brain stimulators and vagus nerve stimulation has been found to be safe and effective for treating specific seizure types.

Temporal lobectomy has been found to be safe and effective for treating patients with complex partial seizures of temporal or extratemporal origin. Patients who have a single identifiable focus in a restricted cortical area that can be safely excised without producing additional disability can be considered as candidates for temporal lobectomy.

Corpus callosotomy has been found to be safe and effective for treating patients with partial and secondarily generalized seizures.

There is only limited evidence that cerebral hemispherectomy is effective in managing unilateral multifocal epilepsy associated with infantile hemiplegia (especially in hemimegalencephaly and Sturge-Weber disease). However, it is the last hope for these patients to eliminate/alleviate their disabling epileptic seizures, and to avoid adverse irreversible psychosocial consequences that may lead to lifelong disability.

Candidates for invasive management of epilepsy and their family, if applicable, should receive detailed information regarding the specific surgical procedures and their possible benefits and side effects. Candidates should not have co-existent progressive neurological disease or major psychological or medical disorder. Persons with progressive neurological diseases or major medical or psychological disorders are generally unsuitable candidates for invasive treatments for epilepsy because of the possibility that surgery could worsen the course of these other conditions.

The Wada test (intra-carotid amytal procedure) is commonly used as a predictor of memory dysfunction following temporal lobectomy for intractable epilepsy. Asymmetry in memory scores can provide focus lateralizing information.

The Agency for Healthcare Research and Quality's technology assessment on the management of treatment-resistant epilepsy stated that the data are inconsistent across studies and do not allow for clear evidence-based conclusions as to the exact proportion of patients who will become seizure-free or who



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will not benefit from multiple subpial transection. In addition, too few studies were available to allow for an evidence-based evaluation of parietal or occipital lobe surgery (Chapell, et al., 2003).

The American Academy of Neurology's practice parameter on temporal lobe and localized neocortical resections for epilepsy stated that there remains no Class I or II evidence regarding the safety and efficacy of localized neocortical resections. Further studies are needed to determine if neocortical seizures benefit from surgery.

MANDATES: None

CODES:

Important note: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT Codes	Description
61534	Craniotomy with elevation of bone flap; for excision of epileptogenic focus without electrocorticography during surgery
61536	Craniotomy with elevation of bone flap; for excision of cerebral epileptogenic focus, with electrocorticography during surgery (includes removal of electrode array)
61537	Craniotomy with elevation of bone flap; for lobectomy, temporal lobe, without electrocorticography during surgery
61538	Craniotomy with elevation of bone flap; for lobectomy, temporal lobe, with electrocorticography during surgery
61541	Craniotomy with elevation of bone flap; for transection of corpus callosum
61543	Craniotomy with elevation of bone flap; for partial or subtotal (functional) hemispherectomy
61736	Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; single trajectory for 1 simple lesion
61737	Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; multiple trajectories for multiple or complex lesion(s)
61850	Twist drill or burr hole(s) for implantation of neurostimulator electrodes, cortical
61860	Craniectomy or craniotomy for implantation of neurostimulator electrodes, cerebral, cortical
61863	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), 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 (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; each additional array (List separately in addition to primary procedure)
61880	Revision or removal of intracranial neurostimulator electrodes



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	<p>61885 - Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array</p> <p>61886 - Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays</p> <p>61888 - Revision or removal of cranial neurostimulator pulse generator or receiver</p> <p>64568 - Open implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator</p> <p>64569 - Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator</p> <p>64570 - Removal of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator</p> <p>64999 - Unlisted procedure, nervous system</p>
CPT Codes Not Covered	N/A
ICD-10 Codes	<p>G40.011 - Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, with status epilepticus</p> <p>G40.019 - Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, without status epilepticus</p> <p>G40.111 - Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, with status epilepticus</p> <p>G40.119 - Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, without status epilepticus</p> <p>G40.211 - Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, with status epilepticus</p> <p>G40.219 - Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, without status epilepticus</p> <p>G40.311 - Generalized idiopathic epilepsy and epileptic syndromes, intractable, with status epilepticus</p> <p>G40.319 - Generalized idiopathic epilepsy and epileptic syndromes, intractable, without status epilepticus</p> <p>G40.411 - Other generalized epilepsy and epileptic syndromes, intractable, with status epilepticus</p> <p>G40.419 - Other generalized epilepsy and epileptic syndromes, intractable, without status epilepticus</p> <p>G40.803 - Other epilepsy, intractable, with status epilepticus</p> <p>G40.804 - Other epilepsy, intractable, without status epilepticus</p> <p>G40.811 - Lennox-Gastaut syndrome, not intractable, with status epilepticus</p> <p>G40.813 - Lennox-Gastaut syndrome, intractable, with status epilepticus</p> <p>G40.814 - Lennox-Gastaut syndrome, intractable, without status epilepticus</p> <p>G40.823 - Epileptic spasms, intractable, with status epilepticus</p> <p>G40.824 - Epileptic spasms, intractable, without status epilepticus</p> <p>G40.911 - Epilepsy, unspecified, intractable, with status epilepticus</p> <p>G40.919 - Epilepsy, unspecified, intractable, without status epilepticus</p>



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POLICY HISTORY:

Status	Date	Action
New	12/17/2010	New policy
Reviewed	12/17/2011	Reviewed.
Reviewed	11/15/2012	Reviewed.
Reviewed	11/14/2013	ICD10 codes added.
Reviewed	09/25/2014	Reviewed
Reviewed	09/24/2015	No changes
Reviewed	09/08/2016	No changes
Reviewed	08/22/2017	Criteria for coverage of responsive cortical stimulation added.
Reviewed	06/05/2018	No changes
Reviewed	08/22/2019	Criteria language updated where necessary. Codes updated
Reviewed	09/24/2020	Criteria updated. Re-formatted for SWHP/FirstCare
Reviewed	09/23/2021	No changes
Reviewed	09/22/2022	Significant revisions
Reviewed	11/29/2023	Formatting changes, added hyperlinks to NCD and TMPPM, beginning and ending note sections updated to align with CMS requirements and business entity changes
Reviewed	03/11/2024	Corrected the Last Review dates and Next Review Dates and corrected the "For Medicaid Plans" section to utilize this Medical Policy if TMPPM does not have medical necessity guidance
Reviewed	09/09/2024	Removed invalid codes from CPT codes list, added descriptors for codes, and minor formatting changes

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. BSWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to BSWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

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Note:

Health Maintenance Organization (HMO) products are offered through Scott and White Health Plan dba Baylor Scott & White Health Plan, and Scott & White Care Plans dba Baylor Scott & White Care Plan. Insured PPO and EPO products are offered through Baylor Scott & White Insurance Company. Scott and White Health Plan dba Baylor Scott & White Health Plan serves as a third-party administrator for self-funded employer-sponsored plans. Baylor Scott & White Care Plan and Baylor Scott & White Insurance Company are wholly owned subsidiaries of Scott and White Health Plan. These companies are referred to collectively in this document as Baylor Scott & White Health Plan.

RightCare STAR Medicaid plans are offered through Scott and White Health Plan in the Central Managed Care Service Area (MRSA) and STAR and CHIP plans are offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSAs.