MEDICAL COVERAGE POLICY	
SERVICE:	**Seizure Disorders: Invasive Treatments (Epilepsy Surgery)**
Policy Number:	**013**
Effective Date:	**04/01/2024**
Last Review:	**03/11/2024**
Next Review:	**03/11/2025**

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.

SERVICE: Seizure Disorders: Invasive Treatments (Epilepsy Surgery)

PRIOR AUTHORIZATION: Required.

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

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 considers 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 hemimegaloencephaly 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.

BSWHP considers 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 considers 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.

Responsive neurostimulation (RNS) (e.g., the NeuroPace RNS System) may be determined 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
   - 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 considers 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 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 hemimegaloencephaly 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 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	61534; 61536; 61537; 61538; 61541; 61543; 61736; 61737; 61850; 61860; 61863; 61864; 61880; 61885; 61886; 61888; 64568; 64569; 64570; 64999; 95961; 95958; 95962; 95970; 95971
CPT Not Covered	N/A

ICD10	G40.011, G40.019 G40.111, G40.119 G40.211, G40.219 G40.311, G40.319 G40.411, G40.419 G40.803, G40.804, G40.811, G40.813, G40.814, G40.823 - G40.824 G40.911, G40.919

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

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.

1. National Institutes of Health Consensus Conference. Surgery for epilepsy. JAMA. 1990;264(6):729-733.
2. Silfvenius H, Dahlgren H, Jonsson E, et al. Surgery for epilepsy [summary]. SBU Report No. 110. Stockholm, Sweden: Swedish Council on Technology Assessment in Health Care (SBU); 1991.
3. Wilensky A. History of focal epilepsy and criteria for medical intractability. Neurosurg Clin N Am. 1993;4(2):193198.
4. Scheuer ML, Pedley TA. The evaluation and treatment of seizures. N Engl J Med. 1990;323(21):1468-1474.
5. So EL. Update on epilepsy. Med Clin North Am. 1993;77(1):203-214.
6. Elwes RD, Dunn G, Binnie CD, Polkey CE. Outcome following resective surgery for temporal lobe epilepsy: A prospective follow up study of 102 consecutive cases. J Neurol Neurosurg Psychiatr. 1991;54(11):949-952.
7. Fuiks KS, Wyler AR, Hermann BP, Somes G. Seizure outcome from anterior and complete corpus callosotomy. J Neurosurg. 1991;74(4):573-578.
8. Tinuper P, Andermann F, Villemure JG, et al. Functional hemispherectomy for treatment of epilepsy associated with hemiplegia: Rationale, indications, results, and comparison with callosotomy. Ann Neurol. 1988;24(1):2734.
9. Smith JR, King DW. Current status of epilepsy surgery. J Med Assoc Ga. 1993;82(4):177-180.
10. Holmes GL. Surgery for intractable seizures in infancy and early childhood. Neurology. 1993;43(11 Suppl 5):S28-S37.
11. Roberts DW. The role of callosal section in surgical treatment of epilepsies. Neurosurg Clin N Am. 1993;4(2):293-300.
12. Adelson PD, Black PM, Madsen JR, et al. Use of subdural grids and strip electrodes to identify a seizure locus in children. Pediatr Neurosurg. 1995;22(4):174-180.
13. Luders H, Hahn J, Lesser RP, et al. Basal temporal subdural electrodes in the evaluation with patients with intractable seizures. Epilepsia. 1989;30(2):131-142.
14. Chung SS, Lee KH, Chang JW, Park YG. Surgical management of intractable epilepsy. Stereotact Funct Neurosurg. 1998;70(2-4):81-88.
15. Chilcott J, Howell S, Kemeny A, et al. The effectiveness of surgery in the management of epilepsy. Guidance Notes for Purchasers; 99/06. Sheffield, UK: University of Sheffield, Trent Institute for Health Services Research; 1999.
16. Alpherts WC, Vermeulen J, van Veelen CW. The wada test: Prediction of focus lateralization by asymmetric and symmetric recall. Epilepsy Res. 2000;39(3):239-249.
17. Bell BD, Davies KG, Haltiner AM, Walters GL. Intracarotid amobarbital procedure and prediction of postoperative memory in patients with left temporal lobe epilepsy and hippocampal sclerosis. Epilepsia. 2000;41(8):992-997.
18. Fernandes MA, Smith ML. Comparing the fused dichotic words test and the intracarotid amobarbital procedure in children with epilepsy. Neuropsychologia. 2000;38(9):1216-1228.
19. Halpern, Casey H. et al. “Deep Brain Stimulation for Epilepsy.” Neurotherapeutics 5.1 (2008): 59–67. PMC. Web. 21 Aug. 2017.
20. Loddenkemper T, Pan A, Neme S, et al. Deep brain stimulation in epilepsy. J Clin Neurophysiol. 2001;18(6):514-532.
21. Benabid AL, Koudsie A, Benazzouz A, et al. Deep brain stimulation of the corpus luysi (subthalamic nucleus) and other targets in Parkinson's disease. Extension to new indications such as dystonia and epilepsy. J Neurol. 2001;248(Suppl 3):III37-III47.
22. Diaz-Arrastia R, Agostini MA, Van Ness PC. Evolving treatment strategies for epilepsy. JAMA. 2002;287(22):2917-2920.
23. Hodaie M, Wennberg RA, Dostrovsky JO, Lozano AM. Chronic anterior thalamus stimulation for intractable epilepsy. Epilepsia. 2002;43(6):603-608.
24. Chabardes S, Kahane P, Minotti L, et al. Deep brain stimulation in epilepsy with particular reference to the subthalamic nucleus. Epileptic Disord. 2002;4 Suppl 3:S83-S93.
25. Zimmerman RS, Sirven JI. An overview of surgery for chronic seizures. Mayo Clin Proc. 2003;78(1):109-117.
26. Engel J Jr, Wiebe S, French J, et al. Practice parameter: Temporal lobe and localized neocortical resections for epilepsy:

Report of the Quality Standards Subcommittee of the American Academy of Neurology, in association with the American Epilepsy Society and the American Association of Neurological Surgeons. Neurology. 2003;60(4):538-547.
27. Chapell R, Reston J, Snyder D. Management of treatment-resistant epilepsy. Evidence Report/Technology Assessment No. 77. Prepared by the ECRI Evidence-based Practice Center under Contract No 290-97-0020. AHRQ Publication No. 03-0028. Rockville, MD: Agency for Healthcare Research and Quality (AHRQ); May 2003. Available at: http://www.ahrq.gov/clinic/evrptpdfs.htm#trepilep. Accessed June 7, 2005.
28. Theodore WH, Fisher RS. Brain stimulation for epilepsy. Lancet Neurol. 2004;3(2):111- 118.
29. Kerrigan JF, Litt B, Fisher RS, et al. Electrical stimulation of the anterior nucleus of the thalamus for the treatment of intractable epilepsy. Epilepsia. 2004;45(4):346-354.
30. Goodman JH. Brain stimulation as a therapy for epilepsy. Adv Exp Med Biol. 2004;548:239-247.
31. Nilsen KE, Cock HR. Focal treatment for refractory epilepsy: Hope for the future? Brain Res Brain Res Rev. 2004;44(2-3):141-153.
32. Marson A, Ramaratnam S. Epilepsy. In: BMJ Clinical Evidence. London, UK: BMJ Publishing Group; updated November 2005.
33. Pichon Riviere A, Augustovski F, Cernadas C, et al. Epilepsy surgery [summary]. Report IRR No. 18. Buenos Aires, Argentina: Institute for Clinical Effectiveness and Health Policy (IECS); December 2003.
34. Kelly K, Theodore WH. Prognosis 30 years after temporal lobectomy. Neurology. 2005;64(11):1974-1976.
35. Velasco F, Carrillo-Ruiz JD, Brito F, et al. Double-blind, randomized controlled pilot study of bilateral cerebellar stimulation for treatment of intractable motor seizures. Epilepsia. 2005;46(7):1071-1081.
36. Gallo BV. Epilepsy, surgery, and the elderly. Epilepsy Res. 2006;68 Suppl 1:S83-S86.
37. Morrell M. Brain stimulation for epilepsy: Can scheduled or responsive neurostimulation stop seizures? Curr Opin Neurol. 2006;19(2):164-168.
38. Tellez-Zenteno JF, McLachlan RS, Parrent A, et al. Hippocampal electrical stimulation in mesial temporal lobe epilepsy. Neurology. 2006;66(10):1490-1494.
39. Halpern C, Hurtig H, Jaggi J, et al. Deep brain stimulation in neurologic disorders. Parkinsonism Relat Disord. 2007;13(1):1-16.
40. Boon P, Vonck K, De Herdt V, et al. Deep brain stimulation in patients with refractory temporal lobe epilepsy.
41. Epilepsia. 2007;48(8):1551-1560.
42. Pollo C, Villemure JG. Rationale, mechanisms of efficacy, anatomical targets and future prospects of electrical deep brain stimulation for epilepsy. Acta Neurochir Suppl. 2007;97(Pt 2):311-320.
43. Velasco AL, Velasco F, Velasco M, et al. Electrical stimulation of the hippocampal epileptic foci for seizure control: A double-blind, long-term follow-up study. Epilepsia. 2007;48(10):1895-1903.
44. Sun FT, Morrell MJ, Wharen RE Jr. Responsive cortical stimulation for the treatment of epilepsy. Neurotherapeutics. 2008;5(1):68-74.
45. Bartolomei F, Hayashi M, Tamura M, et al. Long-term efficacy of gamma knife radiosurgery in mesial temporal lobe epilepsy. Neurology. 2008;70(19):1658-1663.
46. Spencer SS. Gamma knife radiosurgery for refractory medial temporal lobe epilepsy: Too little, too late? Neurology. 2008;70(19):1654-1655.
47. Barbaro NM, Quigg M, Broshek DK, et al. A multicenter, prospective pilot study of gamma knife radiosurgery for mesial temporal lobe epilepsy: Seizure response, adverse events, and verbal memory. Ann Neurol. 2009;65(2):167-175.
48. Troster AI. Neuropsychology of deep brain stimulation in neurology and psychiatry. Front Biosci. 2009;14:18571879.
49. Vojtech Z, Vladyka V, Kalina M, et al. The use of radiosurgery for the treatment of mesial temporal lobe epilepsy and long-term results. Epilepsia. 2009;50(9):2061-2071.
50. Malikova H, Vojtech Z, Liscak R, et al. Stereotactic radiofrequency amygdalohippocampectomy for the treatment of mesial temporal lobe epilepsy: Correlation of MRI with clinical seizure outcome. Epilepsy Res. 2009;83(2-3):235-242.
51. Alvarez, Norberto, Stoppler, Melissa Conrad. Pediatric Epilepsy Surgery available at http://www.medicinenet.com/pediatric_epilepsy_surgery/article.htm , updated 2016.
52. Jayalakshmi, Sita et al. “Surgery for Childhood Epilepsy.” Annals of Indian Academy of Neurology 17.Suppl 1 (2014): S69–

S79. PMC. Web. 21 Aug. 2017.

53. Cascino, Gregory D. Surgical treatment of epilepsy in adults. Up-to-date updated May 12, 2017. Accessed at https://www.uptodate.com/contents/surgical-treatment-of-epilepsy-in-adults.
54. Wiebe S, Blume WT, Girvin JP, Eliasziw M; Effectiveness and Efficiency of Surgery for Temporal Lobe Epilepsy Study Group. A randomized, controlled trial of surgery for temporal-lobe epilepsy. N Engl J Med. 2001;345(5):311-318.
55. Engel J Jr, McDermott MP, Wiebe S, et al; Early Randomized Surgical Epilepsy Trial (ERSET) Study Group. Earlysurgical therapy for drug-resistant temporal lobe epilepsy: a randomized trial. JAMA. 2012;307(9):922930.
56. Jobst BC, Cascino GD. Resective epilepsy surgery fordrug-resistant focal epilepsy: a review. JAMA.2015;313(3):285-293.
57. Schachter, Steven C. Overview of the management of epilepsy in adults. Up-to-date updated April 25, 2022. Accessed at https://www.uptodate.com/contents/overview-of-the-management-of-epilepsy-in-adults.\

***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.