Clinical Policy: Vigabatrin (Sabril, Vigafyde)

Reference Number: CP.PHAR.169
Effective Date: 02.01.16
Last Review Date: 08.24
Line of Business: HIM, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Vigabatrin (Sabril®, Vigafyde™) is an anticonvulsant.

FDA Approved Indication(s)

Sabril is indicated:

- For the treatment of refractory complex partial seizures as adjunctive therapy in patients ≥ 2 years of age who have responded inadequately to several alternative treatments and for whom the potential benefits outweigh the risk of vision loss; Sabril is not indicated as a first line agent for complex partial seizures.
- For the treatment of infantile spasms as monotherapy in infants 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.

Vigafyde is indicated as monotherapy for the treatment of infantile spasms in pediatric patients 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Sabril and Vigafyde are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Infantile Spasms (must meet all)**:**

1. Diagnosis of infantile spasms;
2. Prescribed by or in consultation with a neurologist;
3. Age between 1 month to 2 years;
4. Dose does not exceed 150 mg/kg per day.

Approval duration: 3 months

B. Refractory Complex Partial Seizures (must meet all)**:**

1. Diagnosis of refractory complex partial seizures;
2. Request is for Sabril;
3. Prescribed by or in consultation with a neurologist;
4. Age ≥ 2 years;
5. Sabril will be used as adjunctive therapy;

6. Member meets one of the following (a or b):
   a. Request is for the treatment of a member in a State with limitations on step therapy in certain settings (*see Appendix D*);
   b. Failure of three preferred alternative anticonvulsant drugs (*see Appendix B for examples*);
7. Dose does not exceed any of the following (a or b):
   a. Pediatric members aged 2 to 16 years (*members > 60 kg should be dosed as adults*) (i and ii):
      i. 2,000 mg per day;
      ii. 4 tablets or packets per day;
   b. Adults aged ≥ 17 years (i and ii):
      i. 3,000 mg per day;
      ii. 6 tablets or packets per day.

Approval duration: 6 months

C. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Infantile Spasms (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Sabril or Vigafyde for infantile spasms and has received this medication for at least 30 days;
2. Age between 1 month to 2 years;
3. Member is responding positively to therapy;
4. If request is for a dose increase, new dose does not exceed 150 mg/kg per day.

Approval duration: 12 months or up to 2 years of age, whichever is less

B. Refractory Complex Partial Seizures (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Sabril for refractory complex partial seizures and has received this medication for at least 30 days;
2. Member is responding positively to therapy;

3. If request is for a dose increase, new dose does not exceed any of the following (a or b):
   a. Pediatric members aged 2 to 16 years (*members > 60 kg should be dosed as adults*) (i and ii):
      i. 2,000 mg per day;
      ii. 4 tablets or packets per day;
   b. Adults aged ≥ 17 years (i and ii):
      i. 3,000 mg per day;
      ii. 6 tablets or packets per day.

Approval duration: 12 months

C. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Class	Examples	Dose Limit/ Maximum Dose
Anticonvulsants for partial seizures	carbamazepine (Tegretol®), felbamate (Felbatol®), gabapentin (Neurontin®), lamotrigine (Lamictal®), levetiracetam (Keppra®), oxcarbazepine	Varies according to the agent used

Drug Class	Examples	Dose Limit/ Maximum Dose
	(Trileptal®), phenytoin (Dilantin®), tiagabine (Gabitril®), topiramate (Topamax®), valproic acid (Depakene®), divalproex sodium (Depakote®), zonisamide (Zonegran®)	

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications / Boxed Warnings

- Contraindication(s): none reported
- Boxed warnings: permanent vision loss

Appendix D: States with Limitations against Redirections in Certain Settings

State	Step Therapy Prohibited?	Notes
NV	No	**Applies to Medicaid requests only** Failure of ONE alternative anticonvulsant drug (*see Appendix B for examples*), unless all are contraindicated or clinically significant adverse effects are experienced.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Infantile spasms	50 mg/kg/day (25 mg/kg PO BID); increase total daily dose in increments of 25 mg/kg/day PO every 3 days to 50 mg/kg/day	150 mg/kg/day (75 mg/kg twice daily)
Complex partial seizures	Adults (≥ 17 years): 1,000 mg/day (500 mg PO BID); increase total daily dose weekly in 500 mg/day increments to 3,000 mg/day Pediatrics (2-16 years): • Weight 10-15 kg: 175 mg PO BID to 525 mg PO BID • Weight > 15 kg to 20 kg: 225 mg PO BID to 650 mg PO BID • Weight > 20 kg to 25 kg: 250 mg PO BID to 750 mg PO BID • Weight > 25 kg to 60 kg: 250 mg PO BID to 1,000 mg PO BID • Patients weighing > 60 kg should be dosed according to adult recommendations.	Adults: 3,000 mg/day (1,500 mg twice daily) Pediatrics: 2,000 mg/day (1,000 mg twice daily)

VI. Product Availability

Drug Name	Availability
Vigabatrin (Sabril)	Tablet: 500 mg Powder for oral solution: 500 mg

Drug Name	Availability
Vigabatrin (Vigafyde)	Oral solution: 100 mg/mL

VII. References

1. Sabril Prescribing Information. Deerfield, IL: Lundbeck. October 2021. Available at https://www.sabril.net/prescribing-sabril. Accessed May 13, 2024.
2. Vigafyde Prescribing Information. Parsippany, NJ: Pyros Pharmaceuticals, Inc. June 2024. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/217684s000lbl.pdf. Accessed June 28, 2024.
3. Hancock EC, Osborne JP, Edwards SW. Treatment of infantile spasms. Cochrane Epilepsy Group – Cochrane Database of Syst Rev. June 5, 2013; 6: CD001770. doi: 10.1002/14651858.CD001770.pub3.
4. Pellock JM, Hrachovy R, Shinnar S, et al. Infantile spasms: A U.S. consensus report. Epilepsia. October 2010; 51(10): 2175-89. doi: 10.1111/j.1528-1167.2010.02657.x.
5. Go CY, Mackay MT, Weiss SK, et al. Evidence-based guideline update: Medical treatment of infantile spasms. Report of the Guideline Development Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society. Neurology. June 12, 2012; 78(24): 1974-80. doi: 10.1212/WNL.0b013e318259e2cf.
6. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/. Accessed May 12, 2022.
7. Kanner AM, et al. Practice guideline update summary: efficacy and tolerability of the new antiepileptic drugs I: treatment of new-onset epilepsy. Neurology 2018;91:74-81.
8. Kanner AM, et al. Practice guideline update summary: efficacy and tolerability of the new antiepileptic drugs II: treatment-resistant epilepsy. Neurology 2018;91:82-90.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2020 annual review: no significant changes; references reviewed and updated.	05.04.20	08.20
3Q 2021 annual review: no significant changes; revised HIM.PHAR.21 to HIM.PA.154; references reviewed and updated.	04.20.21	08.21
3Q 2022 annual review: no significant changes; references reviewed and updated.	05.12.22	08.22
Template changes applied to other diagnoses/indications.	09.30.22	
3Q 2023 annual review: no significant changes; references reviewed and updated.	05.18.23	08.23
For refractory complex partial seizures, added redirection bypass for members in a State with limitations on step therapy in certain settings along with Appendix D, which includes Nevada with requirements for single drug redirection for Medicaid requests.	08.31.23	
3Q 2024 annual review: no significant changes; references reviewed and updated. RT4: added newly FDA-approved Vigafyde oral solution to the criteria.	06.28.24	08.24

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members

and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.