Clinical Policy: Vigabatrin (Sabril)

Reference Number: ERX.SPA.73
Effective Date: 10.01.16
Last Review Date: 08.21
Line of Business: Commercial, Medicaid

Revision Log

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

Description

Vigabatrin (Sabril®) 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
- 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

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Sabril is **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. Prescribed by or in consultation with a neurologist;
3. Age ≥ 2 years;
4. Sabril will be used as adjunctive therapy;
5. Failure of three preferred alternative anticonvulsant treatments (*see Appendix B for examples*);
6. Dose does not exceed any of the following (a or b):
   a. Pediatric members aged 2 to 16 years: 2,000 mg (4 tablets or packets) per day (*members > 60 kg should be dosed as adults*);
   b. Adults age ≥ 17 years: 3,000 mg (6 tablets or packets) per day.

Approval duration: 6 months

C. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Sabril 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 a health plan affiliated with Envolve Pharmacy Solutions, 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: 2,000 mg (4 tablets or packets) per day (*members > 60 kg should be dosed as adults*);
   b. Adults age ≥ 17 years: 3,000 mg (6 tablets or packets) per day.

Approval duration: 12 months

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 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 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 (Trileptal®), phenytoin (Dilantin®), tiagabine (Gabitril®), topiramate (Topamax®), valproic acid (Depakene®), divalproex sodium (Depakote®), zonisamide (Zonegran®)	Varies according to the agent used

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 warning(s): permanent vision loss

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Complex partial seizures	Adults (> 17 years): 1,000 mg/day (500 mg twice daily); increase total daily dose weekly in 500 mg/day increments, to 3,000 mg/day Pediatrics (2-16 years): 500 mg/day (250 mg twice daily); increase total daily dose weekly in 500 mg/day increments, to 2,000 mg/day; Patients weighing more than 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)
Infantile spasms	50 mg/kg/day (25 mg/kg twice daily); increase total daily dose every 3 days, in increments of 25 mg/kg/day to 50 mg/kg/day	150 mg/kg/day (75 mg/kg twice daily)

VI. Product Availability

- Tablet: 500 mg
- Powder for oral solution: 500 mg

VII. References

1. Sabril Prescribing Information. Deerfield, IL: Lundbeck. January 2020. Available at https://www.sabril.net/prescribing-sabril. Accessed April 20, 2021.
2. 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.
3. 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.
4. 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.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. Available at: http://www.clinicalpharmacology-ip.com/. Accessed April 20, 2021.
6. 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.
7. 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
Policy split from USS.CP.PHAR.56 HP Acthar and Sabril and converted to new template. Criteria: added maximum doses per PI. Changed age restriction from ≥ 16 years to ≥ 10 years for CPS per PI. Removed all safety criteria.	07.16	09.16
Converted to new template. For infantile spasms: removed Sabril will be used as monotherapy. Other seizure medications are available without a PA making verification problematic. Added criteria of abnormal electroencephalogram (EEG) confirming diagnosis of infantile spasms.	07.01.17	08.17
3Q 2018 annual review: infantile spasms- removed abnormal EEG requirement to confirm diagnosis and added specialist requirement, added back age requirement on re-authorization, extended initial/continued approval duration from 4 weeks/6 months to 3/12 months or up to 2 years of age, whichever is less; complex partial seizures- added specialist requirement; extended initial/continued approval duration from 3/6 to 6/12 months; modified continued therapy to allow for COC for infantile spasms and complex partial seizures; references reviewed and updated.	04.06.18	08.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2019 annual review: no significant changes; for complex partial onset seizures: changed criteria verbiage from “inadequate response” to “failure of”, clarified to require failure of two alternatives; references reviewed and updated.	05.05.19	08.19
RT4: Changed age restriction from 10 years to 2 years for CPS per PI.	02.10.20	
3Q 2020 annual review: changed requirement for complex refractory partial seizures to a prior trial of three preferred alternatives, instead of two; references reviewed and updated.	05.04.20	08.20
3Q 2021 annual review: no significant changes; references reviewed and updated.	04.20.21	08.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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