Clinical Policy: Vigabatrin (Sabril)

Reference Number: ERX.SPA.73
Effective Date: 10.01.16
Last Review Date: 08.17

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
Sabril is indicated:

- For the treatment of refractory complex partial seizures as adjunctive therapy in patients ≥10 years of age who have responded inadequately to several alternative treatments; Sabril is not indicated as a first line agent
- 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

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

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. Age between 1 month to 2 years;
3. Abnormal electroencephalogram (EEG) confirms diagnosis of infantile spasms;
4. Dose does not exceed 150 mg/kg/day.

Approval duration: 4 weeks

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

1. Diagnosis of refractory complex partial seizures;
2. Age ≥ 10 years;
3. Sabril will be used as adjunctive therapy;
4. Inadequate response to ≥ 2 alternative treatments (e.g., carbamazepine, phenytoin);
5. Dose does not exceed (a or b):
   a. Pediatric members age 10 to 16 years: 1000 mg twice daily (*members > 60 kg should be dosed as adults*);
   b. Adults age ≥ 17 years: 1500 mg twice daily (3000 mg/day).

Approval duration: 3 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 member has previously met initial approval criteria;
2. Member is responding positively to therapy;

3. If request is for a dose increase, new dose does not exceed 150 mg/kg/day.

Approval duration: 6 months

B. Refractory Complex Partial Seizures (must meet all):
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed (a or b):
   a. Pediatric members age 10 to 16 years: 1000 mg twice daily (*members > 60 kg should be dosed as adults*);
   b. Adults age ≥ 17 years: 1500 mg twice daily.

Approval duration: 6 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
ILAE: International League Against Epilepsy

Appendix B: International League Against Epilepsy (ILAE) 2010 Seizure Classification

- Generalized seizures
- Tonic-clonic (in any combination)
- Absence
- Typical
- Atypical
- Absence with special features
- Myoclonic absence
- Eyelid myoclonia
- Myoclonic
- Myoclonic atonic
- Myoclonic tonic
- Clonic
- Tonic
- Atonic
- Focal seizures (limited to one hemisphere; includes complex partial seizures)
- Unknown
- Epileptic spasms (includes infantile spasms)

ILAE 2010 descriptors of focal seizures according to degree of impairment during seizure:

- Without impairment of consciousness or awareness.
- With observable motor or autonomic components. This roughly corresponds to the concept of "simple partial seizure. "Focal motor" and "autonomic" are terms that may adequately convey this concept depending on the seizure manifestations).
- Involving subjective sensory or psychic phenomena only. This corresponds to the concept of an aura.
- With impairment of consciousness or awareness. This roughly corresponds to the concept of complex partial seizure. "Dyscognitive" is a term that has been proposed for this concept.
- Evolving to a bilateral, convulsive seizure (involving tonic, clonic, or tonic and clonic components). This expression replaces the term "secondarily generalized seizure."

Appendix C: Therapeutic Alternatives

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
Tegretol (carbamazepine)	Adults and children ≥ 12 years: 200 mg twice daily Children 6-11 years: 100 mg twice daily	Adults >17 years: 1600 mg per day Children 12-15 years: 1200 mg per day Children 6-11 years: 1000 mg per day
Dilantin (phenytoin)	4 to 8 mg/kg/day in divided doses	Varies

Appendix D: Black Box Warning – Permanent Vision Loss

- Sabril can cause permanent bilateral concentric visual field constriction, including tunnel vision that can result in disability. In some cases, Sabril may also decrease visual acuity.
- Risk increases with increasing dose and cumulative exposure, but there is no dose or exposure to Sabril known to be free of risk of vision loss.
- Risk of new and worsening vision loss continues as long as Sabril is used, and possibly after discontinuing Sabril.
- Baseline and periodic vision assessment is recommended for patients on Sabril. However, this assessment cannot always prevent vision damage.
- Sabril is available only through a restricted program called the Vigabatrin REMS Program.

Because of the risk of permanent vision loss, Sabril is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Vigabatrin REMS Program. Further information is available at www.vigabatrinrems.com or 1-866-205-3072.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Complex partial seizures	Adults (> 17 years): 1000 mg/day (500 mg twice daily); increase total daily dose weekly in 500 mg/day increments, to 3000 mg/day Pediatrics (10-16 years): 500 mg/day (250 mg twice daily); -increase total daily dose weekly in 500 mg/day increments, to 2000 mg/day	Adults: 3000 mg/day (1500 mg twice daily) Pediatrics: 2000 mg/day (1000 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

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3. Korff CM, Wirrell E. International League Against Epilepsy (ILAE) classification of seizures and epilepsy. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2016. Available at UpToDate.com. Accessed January 19, 2017.
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6. 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.
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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

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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