MEDICATION POLICY:
Sabril (vigabatrin)

Applicable Drugs: Sabril (vigabatrin)

Preferred: Vigadrone powder packets for solution, Vigadrone tablets

Non-preferred: Sabril powder packets for solution, Sabril tablets, Vigafyde oral solution

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 10/20/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Documented diagnosis of one of the following conditions A through B AND must meet all criteria listed under applicable diagnosis:
   A. Refractory complex partial seizures
      i. Documented failure of at least two alternative anti-epileptic drugs for complex partial seizures.
      ii. Vigabatrin will be used as adjunctive therapy.
      iii. Minimum age requirement: 2 years old.
   B. Infantile spasms
      i. Vigabatrin will be used as monotherapy.
      ii. Age is between 1 month and 2 years old.

II. Treatment is prescribed by or in consultation with a neurologist, and the provider or the provider's healthcare setting is certified in the Vigabatrin REMS Program.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

N/A

OTHER CRITERIA

- Sabril should be discontinued if a significant clinical response is not achieved within 3 months of initiation (for treatment of refractory complex partial seizures) and within 2 to 4 weeks of initiation (for treatment of infantile spasms), or if clinical failure is obvious earlier.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Up to 180 tablets or packets per 30 days

APPROVAL LENGTH

- **Authorization:** 3 months
- **Re-Authorization:** 1 year. An updated letter of medical necessity or progress notes showing a significant clinical response has been achieved and documentation that vision is being monitored periodically (or that patient is formally exempted from periodic ophthalmologic assessment).

APPENDIX

N/A

REFERENCES

1. Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs I: Treatment of new-onset epilepsy: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Epilepsy Society. *Neurology*. 2018;91(2):74-81. doi:10.1212/WNL.0000000000005755
2. Sabril. Prescribing Information. Lundbeck; 2021. Accessed October 20, 2025. https://www.lundbeck.com/content/dam/lundbeck-com/americas/united-states/products/neurology/sabril_pi_us_en.pdf
3. Vigafyde. Prescribing Information. Pyros Pharmaceuticals, Inc.; 2025. Accessed October 20, 2025. https://pyrospharma.com/docs/vigafyde-pi.pdf
4. Vigadrone tablet. Prescribing Information. Upsher-Smith Laboratories, LLC; 2025. Accessed October 20, 2025. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=5e5e7554-d0f4-47f7-a434-cc5ca5a9826f&
5. Vigadrone powder, for solution. Prescribing Information. Upsher-Smith Laboratories, LLC; 2025. Accessed October 20, 2025.

   https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=01f7f049-78c2-47c2-a66e-ec662ba48a98&type=display

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.