PRIOR AUTHORIZATION POLICY

POLICY: Antiseizure Medications – Vigabatrin Prior Authorization Policy

- Sabril® (vigabatrin tablets and powder for solution – Lundbeck, generic)
- Vigpoder™ (vigabatrin powder for oral solution – Pyros [branded generic to Sabril powder for solution])
- Vigadrone® (vigabatrin tablets and oral solution – Upsher-Smith [branded generic to Sabril])
- Vigafyde™ (vigabatrin oral solution – Pyros)

REVIEW DATE: 04/23/2025

OVERVIEW

Vigabatrin (Sabril, generic) is indicated for the following uses:[1-3]

- **Infantile spasms**, as monotherapy, in patients 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.
- **Refractory complex partial seizures**, as adjunctive therapy, in patients ≥ 2 years of age who have inadequately responded to several alternative treatments and for whom the potential benefits outweigh the risk of vision loss. Vigabatrin is not indicated as a first-line agent for complex partial seizures.

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.[4]

According to the vigabatrin prescribing information, use the lowest dosage and shortest exposure to vigabatrin consistent with clinical objectives.[1-4] In patients with infantile spasms, vigabatrin should be withdrawn if a substantial clinical benefit is not observed within 2 to 4 weeks. In patients with refractory complex partial seizures, vigabatrin should be withdrawn if a substantial clinical benefit is not observed within 3 months of initiating treatment.[1-3]

Safety

Vigabatrin has a Boxed Warning with regard to permanent vision loss.[1-4] In some cases, vigabatrin can also damage the central retina and may decrease visual acuity. The onset of vision loss from vigabatrin is unpredictable, and can occur within weeks of starting treatment or sooner, or at any time after starting treatment, even after months or years. The risk of vision loss increases with increasing dose and cumulative exposure, but there is no dose or exposure known to be free of risk of vision loss. Vision assessment is recommended at baseline (no later than 4 weeks after starting vigabatrin), at least every 3 months during therapy, and about 3 to 6 months after the discontinuation of therapy. Once detected, vision loss due to vigabatrin is not reversible. Because of the risk of vision loss, vigabatrin should be withdrawn from patients with refractory complex partial seizures who fail to show substantial clinical benefit within 3 months of initiation and within 2 to 4 weeks of initiation for patients with infantile spasms, or sooner if treatment failure becomes obvious. Because of the risk of permanent vision loss, vigabatrin is available only through a restricted access program under a Risk Evaluation and Mitigation Strategy (REMS) called the Vigabatrin REMS Program.

In 2012, the American Academy of Neurology (AAN) and the Child Neurology Society updated the evidence-based guideline for the medical treatment of infantile spasms (retired April 15, 2024).[5] The guidelines note that low-dose adrenocorticotropic hormone (ACTH) is a first-line agent for the short-term treatment of infantile spasms. ACTH or vigabatrin may be useful for short-term treatment of infantile spasms, with ACTH considered preferentially over vigabatrin. Hormonal therapy (ACTH or prednisolone) may be considered for use in preference to vigabatrin in infants with cryptogenic infantile spasms, to possibly improve developmental outcome. A shorter lag time to treatment of infantile spasms with either hormonal therapy or vigabatrin possibly improves long-term developmental outcomes. The Infantile Spasms Working Group (ISWG) published a US consensus report on infantile spasms in 2010.[6] Data regarding ACTH use and vigabatrin use in infantile spasms were detailed. ACTH is an effective first-line therapy for infantile spasms. Vigabatrin is considered a drug of first choice for infantile spasms with concomitant tuberous sclerosis complex, and it is the drug of second or third choice for children with other symptomatic or cryptogenic infantile spasms.

The AAN and the American Epilepsy Society published a guideline update for treatment-resistant epilepsy (2018) that notes clobazam is probably effective as add-on therapy for Lennox-Gastaut syndrome and is possibly effective as add-on therapy for treatment-resistant adult focal epilepsy.[7] Vigabatrin is effective as add-on therapy in treatment-resistant adult focal epilepsy based on two Class I studies, but it should not be used as a first-line treatment. The benefits of vigabatrin should be weighed against the risks, particularly the risk of irreversible retinopathy.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of vigabatrin. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with vigabatrin as well as the monitoring required for adverse events and long-term efficacy, initial approval requires vigabatrin to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of vigabatrin is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Infantile Spasms.** Approve for 6 months if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≤ 2 years of age; AND
   - **B)** Vigabatrin is being used as monotherapy; AND
   - **C)** The medication is prescribed by or in consultation with a neurologist.

2. **Treatment-Refractory Complex Partial Seizures.** Approve for the duration noted below if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 3 months if the patient meets ALL of the following (i, ii, and iii):
     - **i.** Patient is ≥ 2 years of age; AND
     - **ii.** Patient has tried and/or is concomitantly receiving at least three other antiseizure medications; AND

Note: Examples of antiseizure medications include valproic acid, gabapentin, phenytoin, carbamazepine, oxcarbazepine, lacosamide, levetiracetam, zonisamide, Fycompa (perampanel tablet or oral suspension), lamotrigine, topiramate, rufinamide, tiagabine, felbamate, Diacomit (stiripentol capsules or oral suspension), and clobazam.

iii. The medication is prescribed by or in consultation with a neurologist; OR

B) Patient is Currently Receiving Vigabatrin. Approve for 1 year if the patient is responding to therapy (e.g., reduced seizure severity, frequency, and/or duration) as determined by the prescriber.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of vigabatrin is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Sabril® tablets and powder for oral solution [prescribing information]. Deerfield, IL: Lundbeck; October 2021.
2. Vigpoder™ powder for oral solution [prescribing information]. Parsippany, NJ: Pyros; July 2023.
3. Vigadrone® powder for oral solution [prescribing information]. Maple Grove, MN: Upsher-Smith; January 2024.
4. Vigafyde™ oral solution [prescribing information]. Parsippany, NJ: Pyrose; June 2024.
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*. 2012;78:1974-1980.
6. Pellock JM, Hrachovy R, Shinnar S, et al. Infantile spasms: a US consensus report. *Epilepsia*. 2010;51(10):2175-2189.
7. Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs II: Treatment-resistant epilepsy. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Epilepsy Society. *Neurology*. 2018;91:82-90.