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Section:	Prescription Drugs	**Effective Date:**	January 1, 2026
Subsection:	Neuromuscular Drugs	**Original Policy Date:**	December 10, 2014
Subject:	Sabril Vigadrone Vigafyde	**Page:**	1 of 5

Last Review Date: December 12, 2025

Sabril Vigadrone Vigafyde

Description

Sabril, Vigadrone, Vigafyde (vigabatrin)

Background
Although its complete mechanism of action is unknown, the anti-epileptic drug (AED) vigabatrin targets the enzyme GABA-transferase (GABA-T), which breaks down the central nervous neurotransmitter GABA. Limiting the action of GABA-T helps to increase levels of GABA and potentially lessen frequency of seizures of the complex partial type that have been refractory to prior therapies. Vigabatrin also treats infantile spasms in children 2 years of age or under (1-3).

Regulatory Status
FDA-approved indications: Vigabatrin is an antiepileptic drug (AED) indicated for (1-3):

1. Refractory complex partial seizures – Sabril/Vigadrone are indicated in patients 2 years of age or older. It should be used as adjunctive therapy in patients who have responded inadequately to several alternative treatments.
2. Infantile Spasms - monotherapy in infants 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.

<u>Off-Label Use:</u>
Refractory complex partial seizures in patients 3-9 years of age:
The majority of patients included in the original clinical trials that evaluated the use of vigabatrin for the treatment of refractory partial seizures were adults, and therefore efficacy and safety had not been established in this age group at that time. However, further studies conducted have demonstrated that the use of vigabatrin is effective in decreasing seizure frequency in this

population of pediatric patients compared with baseline (4-5).

Vigabatrin may cause temporary or permanent vision symptoms, including double vision and blurring, and has boxed warnings for vision loss that may continue after ending therapy; including possible permanent loss. Patients, prescribers, and pharmacies must all be enrolled in Vigabatrin REMS program. For patients receiving Vigabatrin, vision assessment is recommended at baseline (no later than 4 weeks after starting therapy), at least every 3 months while on therapy, and about 3-6 months after the discontinuation of therapy. Similar to other AEDs, vigabatrin also increases the risk of depression and suicide; patients should be monitored for mood or behavior changes (1-3).

Related policies
Acthar gel

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Vigabatrin may be considered **medically necessary** if the conditions indicated below are met.

Vigabatrin may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Infantile spasms
    a. Used as monotherapy
2. Refractory complex partial seizures (CPS)
    a. Inadequate response, intolerance, or contraindication to alternate treatments

AND ALL of the following:

1. Patient and prescriber are enrolled in the Vigabatrin REMS program

2. Baseline vision assessment and confirmation vision will be assessed every 3 months during therapy
3. **Sabril and Vigafyde only:** Inadequate treatment response, intolerance, or contraindication to **BOTH** generic vigabatrin **AND** Vigadrone

Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Infantile spasms
    a. Used as monotherapy
2. Refractory complex partial seizures (CPS)

AND ALL of the following:

1. Vision will be assessed every 3 months during therapy
2. Patient and prescriber are enrolled in the Vigabatrin REMS program
3. **Sabril and Vigafyde only:** Inadequate treatment response, intolerance, or contraindication to **BOTH** generic vigabatrin **AND** Vigadrone

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Vigabatrin is an anti-epileptic drug that targets the enzyme, GABA-transferase (GABA-T) which breaks down the central nervous neurotransmitter GABA. Limiting the action of GABA-T helps to increase levels of GABA and potentially lessen frequency of seizures; it also treats infantile

spasms. Vigabatrin has boxed warnings for the risk of vision loss, possibly permanent, in some cases (1-3).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of vigabatrin while maintaining optimal therapeutic outcomes.

References

1. Sabril [package insert]. Deerfield, IL: Lundbeck; October 2021.
2. Vigadrone [package insert]. Maple Grove, MC: Upsher-Smith Laboratories, LLC; March 2023.
3. Vigafyde [package insert]. Parsippany, NJ: Pyros Pharmaceuticals, Inc. June 2024.
4. Greiner HM, Lynch ER et al. Vigabatrin for childhood partial-onset epilepsies. Pediatric Neurology 2012; 46:83 – 88.
5. Nielsen JC, Dwain T, et al. Vigabatrin pediatric dosing information for refractory complex partial seizures: results from a population dose-response analysis. Epilepsia, 55(12):e134–e138, 2014

Policy History

Date	Action
December 2014	Addition to PA
March 2015	Annual review and reference update
September 2015	Annual review
December 2016	Annual editorial review and reference update Addition of the 10 years of age and older to the renewal section for CPS Policy number change from 5.12.05 to 5.75.05
September 2017	Annual editorial review and reference update
March 2018	Removal of age requirements from initiation and renewal section for all indications Addition of patient and prescriber are enrolled in the SHARE REMS program in renewal section
June 2018	Annual review and reference update
May 2019	Changed policy name to Sabril Vigadrone (vigabatrin)
June 2019	Annual review
December 2019	Annual review. Addition of requirement to trial preferred products
September 2020	Annual editorial review and reference update
September 2021	Annual review and reference update
September 2022	Annual review and reference update
December 2022	Annual review
September 2023	Annual review
December 2023	Annual review

September 2024	Annual review
November 2024	Added Vigafyde as non-preferred option to policy, changed name of REMS program to Vigabatrin REMS. Changed policy name to Sabril Vigadrone Vigafyde (vigabatrin)
December 2024	Annual review. Per SME, added vision monitoring frequency to regulatory section
September 2025	Annual review
December 2025	Annual editorial review. Removed MedEx requirement and switched to t/f

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.