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Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Neuromuscular Drugs	**Original Policy Date:**	December 10, 2014
Subject:	Sabril Vigadrone	**Page:**	1 of 5

Last Review Date: September 6, 2024

Sabril Vigadrone

Description

Sabril (**vigabatrin**), **Vigadrone** (**vigabatrin**)

Bolded medications are the preferred products

Background
Although its complete mechanism of action is unknown, the anti-epileptic drug (AED) Sabril/Vigadrone 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. Sabril/Vigadrone also treats infantile spasms in children 2 years of age or under (1-2).

Regulatory Status
FDA-approved indications: Sabril/Vigadrone is an antiepileptic drug (AED) indicated for (1-2):

1. Refractory complex partial seizures – Sabril is indicated in patients 2 years of age or older. Vigadrone is indicated in patients 10 years of age and 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.

Off-Label Use:
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 (3-4).

Sabril/Vigadrone 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 SHARE REMS program. All patients should have a baseline vision check and be periodically monitored for both visual field and acuity. Similar to other AEDs, Sabril/Vigadrone also increases the risk of depression and suicide; patients should be monitored for mood or behavior changes (1-2).

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.

Sabril/Vigadrone may be considered **medically necessary** if the conditions indicated below are met.

Sabril/Vigadrone 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 SHARE REMS program
2. Baseline vision assessment and confirmation vision will be assessed every 3 months during therapy
3. **Brand Sabril only:** Patient **MUST** have tried **ALL** preferred products (generic Sabril: vigabatrin and Vigadrone) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

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 SHARE REMS program
3. **Brand Sabril only:** Patient **MUST** have tried **ALL** preferred products (generic Sabril: vigabatrin and Vigadrone) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Sabril/Vigadrone 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. Sabril/Vigadrone has boxed warnings for the risk of vision loss, possibly permanent, in some cases (1-2).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Sabril/Vigadrone 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; February 2020.
3. Greiner HM, Lynch ER et al. Vigabatrin for childhood partial-onset epilepsies. Pediatric Neurology 2012; 46:83 – 88.
4. 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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.