



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES  
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 7/21/2016  
LAST REVIEW DATE: 8/19/2021  
LAST CRITERIA REVISION DATE: 8/19/2021  
ARCHIVE DATE:

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**SABRIL® (vigabatrin) oral**  
**Vigabatrin oral**  
**VIGADRONE™ (vigabatrin) oral**

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Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at [www.azblue.com/pharmacy](http://www.azblue.com/pharmacy).

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the [request form](#) in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to [Pharmacyprecert@azblue.com](mailto:Pharmacyprecert@azblue.com). **Incomplete forms or forms without the chart notes will be returned.**

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**Criteria:**

- **Criteria for initial therapy:** Sabril (vigabatrin), Vigadrone (vigabatrin) and vigabatrin is considered **medically necessary** when **ALL** of the following criteria are met:
1. Diagnosis is **ONE** of the following:
    - a. Individual is 2 years of age or older with a confirmed diagnosis of refractory complex partial seizures, who has not responded adequately to several alternative treatments **AND** where Sabril, Vigadrone, or Vigabatrin will be used as adjunctive therapy
    - b. Individual is an infant 1 month to 2 years of age with a confirmed diagnosis of infantile spasms **AND** where Sabril, Vigadrone, or Vigabatrin will be used as monotherapy
  2. **Additional criteria for refractory partial complex seizures**, individual has failed, or is intolerant to, or has a contraindication such that the individual is unable to use **THREE** of the following preferred step therapy agents for complex partial seizures:
    - a. Gabapentin
    - b. Lamotrigine
    - c. Levetiracetam
    - d. Oxcarbazepine
    - e. Topiramate
  3. A **baseline test** vision assessment has been completed before initiation of treatment with continued monitoring as clinically appropriate [Note: This is waived if it is verified that Provider, Patient, and Pharmacy are enrolled in the REMS program]
  4. Creatinine clearance is > 10 mL/min
  5. There are no significant interacting drugs

**Initial approval duration:**

3 months

Continuation requires documentation of significant clinical benefit

- **Criteria for continuation of coverage (renewal request):** Sabril (vigabatrin), Vigadrone (vigabatrin) and vigabatrin is considered **medically necessary** with documentation of **ALL** of the following:
1. Individual's condition responded while on therapy
    - a. **For refractory partial complex seizures**, response is defined as **ONE** of the following:
      - i. Achieved and maintains at least a 50% reduction in frequency of complex partial seizures
      - ii. Achieved and maintains at least a 50% reduction in secondary generalized seizures
      - iii. There is no evidence of vision loss

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- b. **For infantile spasms**, response is defined as **ONE** of the following:
- i. Achieved and maintains spasm freedom as assessed by caregiver
  - ii. Achieved and maintains no spasms or hypsarrhythmia during closed circuit television electroencephalography (CCTV EEG)
  - iii. There is no evidence of vision loss
2. Individual has been adherent with the medication
  3. Verification that Prescriber, Patient, and Pharmacy are enrolled in the REMS program
  4. Individual has not developed any significant adverse drug effects that may exclude continued use
    - a. Significant adverse effect such as:
      - i. Vision loss
      - ii. Neurotoxicity
      - iii. Suicide thoughts or behaviors
      - iv. Emerging or worsening depression
      - v. Any unusual change in mood or behavior
      - vi. Peripheral neuropathy
  5. There are no significant interacting drugs

**Renewal duration:**

12 months

Continuation requires documentation of significant clinical benefit

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of a Non-cancer Medications**
2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

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**Description:**

Sabril (vigabatrin), Vigadrone (vigabatrin) and vigabatrin are indicated as adjunctive therapy for adults and pediatric patients 2 years of age or older with refractory complex partial seizures who have inadequately responded to several alternative treatments, they are not indicated as a first line agent for complex partial seizures. They are also indicated as monotherapy for pediatric patients with infantile spasms 1 month to 2 years of age.

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Epilepsy is a neurological disorder where brief disturbances in the electrical function of the brain result in seizures. These seizures may affect consciousness, bodily movements or sensations for a short time. There are several different types of seizure that occur in epilepsy including partial (affecting one area of the brain), generalized (affecting nerve cells throughout the brain), and unclassified.

Anti-epileptic drugs (AED) are effective in controlling seizures. There is insufficient evidence to conclude that one AED is superior to another in controlling partial and generalized seizures or in improving outcomes. The evidence is also insufficient to conclude that branded AED are more effective than generic AED in terms of reducing seizure frequency or improving outcomes. In addition, the evidence is insufficient to support any relevant negative outcome (such as increased seizure frequency, hospitalizations, and mortality) when switching from a branded to a generic medication. However, switching between different manufacturers could lead to variations in serum concentrations and it is suggested that prescription refills should be from the same manufacturer. The FDA maintains that there is no convincing evidence that people with epilepsy have less seizure control when taking generic medications.

All AED are associated with an increased risk of suicidal ideation and suicidal behavior when used in patients with epilepsy. While there is a high degree of variability in tolerability to AEDs, no specific AED is considered to be the safest or best tolerated. Adverse events are common to all AED and include confusion, dizziness, somnolence, ataxia, nausea, and vomiting. Individual AEDs are associated with serious, but rare adverse events. Sabril (vigabatrin) carries a boxed warning and has a REMS program for risk of irreversible vision loss.

Practice guidelines for suggest that choice of treatment should be individualized based on several factors such as drug effectiveness for the seizure type, patient age, concomitant medications, tolerability, safety, response to previous therapy, potential adverse effects of the drug, interactions with other medications, comorbid medical conditions, gender, lifestyle, patient preferences, and cost. Treatment should begin with a single agent with dose titration to achieve control of seizures or development of unacceptable side effects. If seizures persist, another agent is used as monotherapy; some recommend attempting a second alternative before using multiple drugs to control seizures. Achieving a seizure-free state is difficult and many patients may have to try multiple regimens and combination therapies to achieve control of seizures.

Partial seizures are divided into simple partial, complex partial, and partial seizures that evolve into secondary generalized seizures. The difference between simple and complex seizures is that during simple partial seizures, patients retain awareness; during complex partial seizures, they lose awareness.

Infantile spasms (also known as West's syndrome) is a rare epileptic disorder with main characteristics of infantile spasms, mental retardation, and hypsarrhythmia, a specific abnormal pattern detected by an electroencephalogram (EEG) that is described as slow waves of high voltage and random pattern of spikes that vary in duration and location. Infantile spasms are characterized by sudden jerking and bending forward of the body, followed by stiffening of the body. Spasms usually last around 1-5 seconds but can range from 2-500 spasms at any given time.

Use of Sabril (vigabatrin), Vigadrone (vigabatrin) and vigabatrin are subject to a Risk Evaluation and Mitigation Strategies (REMS) program that requires provider, patient, and dispensing pharmacy be enrolled into the program. Only providers and Pharmacies enrolled into the REMS may prescribe and dispense the drug, respectively, to individuals who are also in the program. A REMS program attempts to manage known or



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potentially serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) for some drugs to ensure that the benefits of a drug outweigh its risks.

The precise mechanism of vigabatrin's anti-seizure effect is unknown, but it is believed to be the result of its action as an irreversible inhibitor of  $\gamma$ -aminobutyric acid transaminase (GABA-T), the enzyme responsible for the metabolism of the inhibitory neurotransmitter GABA. Inhibition of GABA-T results in increased levels of GABA in the central nervous system.

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**Definitions:**

**Sabril (vigabatrin), Vigadrone (vigabatrin), vigabatrin REMS items:**

- Enrollment and agreement information
  - Ophthalmologic assessment requirements
  - Treatment initiation information
  - Treatment maintenance information
  - Pharmacy requirements and responsibilities
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**Resources:**

Sabril (vigabatrin) product information, revised by Lundbeck Pharmaceuticals, LLC. 02-2020. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed on July 14, 2021.

Vigabatrin product information, revised by Dr. Reddy's Laboratories, Inc. 03-2020. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed on July 14, 2021.

Vigadrone (vigabatrin) product information, revised by Upsher-Smith Laboratories, LLC. 02-2020. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed on July 14, 2021.

Glaze DG. Management and prognosis of infantile spasms. In: UpToDate, Nordli DR, Dashe JF (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Accessed on July 15, 2021.

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