BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES		**ORIGINAL EFFECTIVE DATE:**	**7/21/16**
SECTION:	**DRUGS**	**LAST REVIEW DATE:**	**8/02/18**
		LAST CRITERIA REVISION DATE:	**8/02/18**
		ARCHIVE DATE:	

SABRIL® (vigabatrin) powder for oral solution and oral tablet
Vigadrone™ (vigabatrin) powder for oral solution
Vigabatrin powder for oral solution

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.

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.

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. **Incomplete forms or forms without the chart notes will be returned.**

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Vigabatrin powder for oral solution (cont.)

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:
     - Individual is 10 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
     - 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. **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:
     - Gabapentin
     - Lamotrigine
     - Levetiracetam
     - Oxcarbazepine
     - Topiramate

  Initial approval duration: 12 months

- **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
     - **For refractory partial complex seizures**, response is defined as **ONE** of the following:
       - Achieved and maintains at least a 50% reduction in frequency of complex partial seizures
       - Achieved and maintains at least a 50% reduction in secondary generalized seizures
       -
     - **For infantile spasms**, response is defined as **ONE** of the following:
       - Achieved and maintains spam freedom as assessed by caregiver
       - Achieved and maintains no spasms or hypsarrhythmia during closed circuit television electroencephalography (CCTV EEG)
  2. Individual has been adherent with the medication

  Renewal duration: 12 months

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Description:

Sabril (vigabatrin) (vigabatrin), Vigadrone (vigabatrin) and vigabatrin are indicated as adjunctive therapy for adults and pediatric patients 10 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.

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

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(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 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 γ-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.

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

Resources:

Sabril. Package Insert. Revised by manufacturer 09/2015. Accessed 05-20-2016.

Sabril. Package Insert. Revised by manufacturer 04-2017. Accessed 07-24-2018.

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

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Office notes, labs, and medical testing relevant to the request that show medical justification are required.