BlueCross BlueShield of Arizona
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PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 9/17/15**
SECTION: DRUGS	**LAST REVIEW DATE: 2/21/19**
	LAST CRITERIA REVISION DATE: 2/21/19
	ARCHIVE DATE:

BANZEL® (rufinamide) oral film-coated tablet and oral suspension

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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Criteria:

- **Criteria for initial therapy:** Banzel (rufinamide) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual is 1 year of age or older

  2. A confirmed diagnosis of adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome

  3. Individual has failure, contraindication or intolerance to **ALL** of the following preferred step therapy agents:
     - Preferred step therapy agents include:
       - Felbamate
       - Lamotrigine
       - Topiramate

  4. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
     - Liver function tests

  5. Individual does not have severe hepatic impairment (Child-Pugh Class C)

  6. There are **NO** contraindications:
     - Contraindications include:
       - Familial Short QT Syndrome

  Initial approval duration: 12 months

- **Criteria for continuation of coverage (renewal request):** Banzel (rufinamide) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual's condition responded while on therapy
     - Response is defined as:
       - Reduction in the number of seizure episodes

  2. Individual has been adherent with the medication

  3. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
     - Contraindications as listed in the criteria for initial therapy section
     - Significant adverse effect such as:
       - DRESS
       - Emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior

BANZEL® (rufinamide) oral film-coated tablet and oral suspension (cont.)

4. There are no significant interacting drugs

Renewal duration: 12 months

Description:

Aptiom (eslicarbazepine acetate) is indicated as monotherapy or adjunctive treatment of partial-onset seizures. Potiga (ezogabine) is indicated as adjunctive treatment of partial-onset seizures in patients who have responded inadequately to several alternative treatments and for whom the benefits outweigh the risk of retinal abnormalities and potential decline in visual acuity. Banzel (rufinamide) is indicated for adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS).

Epilepsy is a neurological disorder where brief disturbances in the electrical function of the brain result in seizures. These seizures may affect consciousness and 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 outcomes (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 AED, 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 AED are associated with serious, but rare adverse events. Ezogabine (Potiga) has a boxed warning for risk of retinal abnormalities and vision loss.

Practice guidelines 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.

Lennox–Gastaut Syndrome (LGS), also known as Lennox syndrome, is a severe and difficult-to-treat form of childhood-onset epilepsy that most often appears between the second and sixth year of life. It is characterized by

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frequent seizures and can include different seizure types, such as, tonic, atonic, atypical absence, and myoclonic seizures. There may be periods of frequent seizures mixed with brief, relatively seizure-free periods. Most children with LGS experience some degree of impaired intellectual functioning or information processing, along with developmental delays and behavioral disturbances.

Treatment for LGS includes AED such as Clobazam, Clonazepam, Felbamate, Lamotrigine, Rufinamide, or Topiramate. There is usually no single antiepileptic medication that will control seizures. Children who improve initially may later show tolerance to a drug or have uncontrollable seizures.

Aptiom (eslicarbazepine) is chemically related to Oxcarbazepine and Carbamazepine. Eslicarbazepine is the active metabolite of Oxcarbazepine.

Resources:

Aptiom. Package Insert. Revised by manufacturer 11/2013. Accessed 07/22/2015.

Aptiom. Package Insert. Revised by manufacturer 08/2015. Accessed 07/22/2016.

Aptiom. Package Insert. Revised by manufacturer 09/2016. Accessed 11/30/2016.

Aptiom. Package Insert. Revised by manufacturer 09/2017. Accessed 12/20/2017.

Banzel. Package Insert. Revised by manufacturer 06/2015. Accessed 07/22/2015, 12/20/2017.

Potiga. Package Insert. Revised by manufacturer 05/2015. Accessed 07/22/2015.

Potiga. Package Insert. Revised by manufacturer 05/2016. Accessed 07/22/2016, 12/20/2017.

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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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