BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

BANZEL® (rufinamide) oral
Rufinamide oral

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require precertification is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

BANZEL (rufinamide)
Rufinamide

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

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Neurologist

  2. Individual is 1 year of age or older

3. Individual has a confirmed diagnosis of adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome

4. Individual has failure, contraindication or intolerance to **ALL** of the following preferred step therapy agents:
    a. Felbamate
    b. Lamotrigine
    c. Topiramate

5. Request for **brand** Banzel: Individual has documented failure, contraindication per FDA label, intolerance to **generic rufinamide**

6. The individual has completed the following baseline test before initiation of treatment with continued monitoring as clinically appropriate: Liver function tests

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

8. There are **NO** FDA-label contraindications, such as: Familial Short QT Syndrome

9. There are no significant interacting drugs

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Banzel (rufinamide) or generic rufinamide is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met (**samples are not considered for continuation of therapy**):

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Neurologist

2. Individual's condition has responded while on therapy with response defined as:
    a. Documented evidence of efficacy, disease stability and/or improvement in the number of seizure episodes
    b. No evidence individual has developed any significant unacceptable adverse drug reactions that may exclude continued use

3. Individual has been adherent with the medication

4. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use
    a. Contraindications as listed in the criteria for initial therapy section
    b. Significant adverse effect such as:
        i. Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) or Multiorgan Hypersensitivity
        ii. Emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior

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

6. There are no significant interacting drugs

Renewal duration: 12 months

- 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 Non-Cancer Medications**

2. **Off-Label Use of Cancer Medications**

Description:

Aptiom (eslicarbazepine acetate) is indicated as monotherapy or adjunctive treatment of partial-onset seizures. Rufinamide (generic or brand Banzel) 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 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.

Resources:

Banzel (rufinamide) product information, revised by Eisai Inc. 04-2020. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed December 16, 2021.

Rufinamide suspension product information, revised by Ascend Laboratories, LLC. 02-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed December 16, 2021.

Rufinamide tablet product information, revised by Mylan Pharmaceutical Inc. 05-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed December 16, 2021.

Karceski S. Initial treatment of epilepsy in adults. In: UpToDate, Garcia P, Dashe JF (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Topic last updated July 19, 2021. Accessed December 16, 2021.

Wilfong A. Seizures and epilepsy in children: Initial treatment and monitoring. In: UpToDate, Nordli DR, Dashe JF (Ed), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Topic last updated September 20, 2021. Accessed December 16, 2021.