MEDICAL MUTUAL®

Drug Policy

Policy:	Banzel (rufinamide)	Annual Review Date: 08/24/2023 Last Revised Date: 08/24/2023

OVERVIEW

Banzel is indicated for adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome in pediatric patients ≥ 1 year of age and in adults.[1]

Although Banzel is only FDA-approved for use in Lennox-Gastaut Syndrome, clinical trial data indicate the drug may also be beneficial as adjunctive treatment of refractory focal epilepsy.[2] A review of six clinical trials found that Banzel when used as an add-on treatment was effective in reducing seizure frequency in patients with drug-resistant focal epilepsy

POLICY STATEMENT

This policy involves the use of Banzel. Prior authorization is recommended for pharmacy benefit coverage of Banzel. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Banzel as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Banzel be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Banzel is recommended in those who meet the following criteria:

For all indications: If brand Banzel is prescribed, the patient must have tried generic rufinamide AND the brand product is being requested due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand product and the bioequivalent generic product which, per the prescribing provider, would result in a significant allergy or serious adverse reaction; AND

1. <u>Lennox-Gastaut Syndrome</u>

Criteria. Approve for 1 year if the patient meets ONE of the following criteria (A <u>or</u> B):

A) Initial Therapy: Approve for 1 year if the patient meets the following criteria (i, ii, and iii):
- **i.** Patient is ≥ 1 year of age; AND
- **ii.** Patient has tried and/or is concomitantly receiving at least two other antiepileptic drugs; AND
  Note: Examples of antiepileptic drugs include valproic acid, gabapentin, phenytoin, carbamazepine, oxcarbazepine, lacosamide, levetiracetam, zonisamide, Fycompa (perampanel tablet or oral suspension), vigabatrin, lamotrigine, topiramate, clobazam, Diacomit (stiripentol capsules or oral suspension), Epidiolex (cannabidiol oral solution), and felbamate.
- **iii.** The medication is prescribed by, or in consultation with, a neurologist.

B) Patient is Currently Receiving rufinamide. Approve if the patient is responding to therapy (e.g., reduced seizure severity, frequency, and/or duration) as determined by the prescriber.

2. Treatment-Refractory Seizures/Epilepsy

Criteria. Approve for 1 year if the patient meets ONE of the following criteria (A or B):

A) Initial Therapy: Approve for 1 year if the patient meets the following criteria (i, ii, and iii):
- **i.** Patient is ≥ 1 years of age; AND
- **ii.** Patient has tried and/or is concomitantly receiving at least two other antiepileptic drugs; AND
  Note: Examples of antiepileptic drugs include valproic acid, gabapentin, phenytoin, carbamazepine, oxcarbazepine, lacosamide, levetiracetam, zonisamide, Fycompa (perampanel tablet or oral suspension), vigabatrin, lamotrigine, topiramate, clobazam, Diacomit (stiripentol capsules or oral suspension), Epidiolex (cannabidiol oral solution), and felbamate.
- **iii.** The medication is prescribed by, or in consultation with, a neurologist.

B) Patient is Currently Receiving rufinamide. Approve if the patient is responding to therapy (e.g., reduced seizure severity, frequency, and/or duration) as determined by the prescriber.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Banzel has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a

pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Banzel® tablets and oral suspension [prescribing information]. Woodcliff Lake, NJ: Eisai Inc.; November 2019.
2. Panebianco M, Prabhakar H, Marson AG. Rufinamide add-on therapy for refractory epilepsy. *Cochrane Database Syst Rev*. 2018;4:CD011772.
3. Sirven JI, Shafer PO. Epilepsy Foundation – Lennox-Gastaut Syndrome. Updated February 2020. Available at: https://www.epilepsy.com/learn/types-epilepsy-syndromes/lennox-gastaut-syndrome-lgs. Accessed on September 11, 2020.
4. Cross JH, Auvin S, Falip M, et al. Expert opinion on the management of Lennox-Gastaut syndrome: treatment algorithms and practical considerations. *Front Neurol*. 2017;8:505.
5. Ostendorf AP, Ng YT. Treatment-resistant Lennox-Gastaut syndrome: therapeutic trends, challenges, and future directions. *Neuropsych Dis Treatment*. 2017;13:1131-1140.
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7. Lennox-Gastaut Syndrome Foundation – Lennox-Gastaut Syndrome. Available at: http://www.lgsfoundation.org/understanding. Accessed on September 11, 2020.
8. Cherian KA. Lennox-Gastaut syndrome treatment & management. Updated August 6, 2020. Available at: https://emedicine.medscape.com/article/1176735-treatment. Accessed on September 11, 2020.