Drug Coverage Policy

Effective Date 5/1/2026
Coverage Policy Number.....IP0048
Policy Title..... Rufinamide

Antiseizure Medications – Rufinamide

- Banzel® (rufinamide tablets and oral suspension – Eisai, generic)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Rufinamide is indicated for adjunctive treatment of **seizures associated with Lennox-Gastaut syndrome** in patients ≥ 1 year of age.[1]

Although rufinamide 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 rufinamide, when used as an add-on treatment, was effective in reducing seizure frequency in patients with drug-resistant focal epilepsy.

Disease Overview
Lennox-Gastaut syndrome, a severe epileptic and developmental encephalopathy, is associated with a high rate of morbidity and mortality.[3,4] Lennox-Gastaut syndrome most often begins between 3 and 5 years of age.[3-6] Affected children experience several different types of seizures, most commonly atonic seizures (sudden loss of muscle tone and limpness) and tonic seizures.[3,6] The three main forms of treatment of Lennox-Gastaut syndrome are antiseizure medications (ASMs), dietary therapy (typically the ketogenic diet), and device/surgery (e.g., vagus nerve stimulation, corpus callostomy).[6] None of the therapies are effective in all cases of Lennox-Gastaut syndrome and the disorder has proven particularly resistant to most therapeutic options.

Guidelines/Recommendations
Lennox-Gastaut Syndrome
Currently, the FDA-approved drugs for this condition are Fintepla® (fenfluramine oral solution), clobazam, clonazepam, rufinamide, Epidiolex® (cannabidiol oral solution), felbamate, lamotrigine, and topiramate.[7] To address the lack of treatment algorithm, the Lennox-Gastaut syndrome Special Interest Group of the Pediatric Epilepsy Research Consortium formed a core working group focused on ASM selection in this patient population (2025). Despite the lack of specific FDA labeling for Lennox-Gastaut syndrome, valproic acid remains a mainstay in treatment.[6,7] Valproic acid is considered a first-line pharmacologic therapy but should be avoided in women of childbearing potential due to potential teratogenic effects.[7] Clobazam is recommended as a first-line option, particularly for managing disabling drop seizures, while it may be considered a second-line option in other cases. Epidiolex may be considered a second-line therapy, specifically when combined with clobazam; otherwise, it is generally listed as a third-line treatment. Many other options are cited in the second- or later-line settings including lamotrigine, rufinamide, topiramate, levetiracetam, brivaracetam, perampanel (Fycompa®, generic), zonisamide, Fintepla, and felbamate; refer to the consensus algorithm for additional detail. Monotherapy is rarely effective in managing Lennox-Gastaut syndrome, which necessitates the use of combination therapy with two or three ASMs with varying mechanisms of action. However, where possible, no more than two ASMs should be used concomitantly; use of multiple ASMs raise the risk of side effects and/or drug-drug interactions.

Coverage Policy

POLICY STATEMENT
Prior Authorization is required for benefit coverage of rufinamide. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with rufinamide as well as the monitoring required for adverse events and long-term efficacy, initial approval requires rufinamide to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Rufinamide products are considered medically necessary when ONE of the following criteria are met:

FDA-Approved Indication

1. **Lennox-Gastaut Syndrome.** Approve for 1 year if the patient meets ONE of the following (A or B):
    - **A.** Initial Therapy. Approve if the patient meets ALL of the following (i, ii, iii, and iv):

i. Patient is ≥ 1 year of age; AND
ii. Patient has tried or is concomitantly receiving at least two other antiseizure medications; AND
Note: Examples of antiseizure medications include valproic acid, gabapentin, phenytoin, carbamazepine, oxcarbazepine, lacosamide, levetiracetam, zonisamide, perampanel, 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; AND
iv. Preferred product criteria is met for the product(s) as listed in the below table(s); OR

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.

Other Uses with Supportive Evidence

2. **Treatment-Refractory Seizures/Epilepsy.** Approve for 1 year if the patient meets ONE of the following (A or B):
   A. Initial Therapy. Approve if the patient meets ALL of the following (i, ii, iii and iv):
      i. Patient is ≥ 1 year of age; AND
      ii. Patient has tried or is concomitantly receiving at least two other antiseizure medications; AND
      Note: Examples of antiseizure medications include valproic acid, gabapentin, phenytoin, carbamazepine, oxcarbazepine, lacosamide, levetiracetam, zonisamide, perampanel, 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; AND
      iv. Preferred product criteria is met for the product(s) as listed in the below table(s); OR
   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.

Employer Plans:

Product	Criteria
Banzel (rufinamide oral suspension)	The patient has tried the bioequivalent generic product **rufinamide oral suspension** AND cannot take due to a formulation difference in the inactive ingredient(s) [for example, difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction.
Banzel (rufinamide tablets)	The patient has tried the bioequivalent generic product **rufinamide tablets** AND cannot take due to a formulation difference in the inactive ingredient(s) [for example, difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction.

Individual and Family Plans:

Product	Criteria
Banzel (rufinamide oral suspension)	The patient has tried the bioequivalent generic product **rufinamide oral suspension** AND cannot take due to a formulation difference in the inactive ingredient(s) [for example, difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction.
Banzel (rufinamide tablets)	The patient has tried the bioequivalent generic product **rufinamide tablets** AND cannot take due to a formulation difference in the inactive ingredient(s) [for example, difference in dyes, fillers, preservatives] between the brand and the bioequivalent generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction.

Conditions Not Covered

Rufinamide for any other use is considered not medically necessary. Criteria will be updated as newly published data are available.

References

1. Banzel® tablets and oral suspension [prescribing information]. Woodcliff Lake, NJ: Eisai; November 2019.
2. Brigo F, Jones K, Eltze C, et al. Anti-seizure medications for Lennox-Gastaut syndrome. *Cochrane Database Syst Rev*. 2021;4(4):CD003277.
3. Sirven JI, Shafer PO. Epilepsy Foundation – Lennox-Gastaut Syndrome. Updated February 2020. Available at: https://www.epilepsy.com/what-is-epilepsy/syndromes/lennox-gastaut-syndrome. Accessed on January 29, 2026.
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.
6. Wheless JW. National Organization for Rare Diseases (NORD) – Lennox-Gastaut syndrome. Updated May 20, 2024. Available at: https://rarediseases.org/rare-diseases/lennox-gastaut-syndrome/. Accessed on January 28, 2026.
7. Samanta D, Bhalla S, Bhatia S, et al. Antiseizure medications for Lennox-Gastaut Syndrome: Comprehensive review and proposed consensus treatment algorithm. *Epilepsy Behav*. 2025;164:110261.

Revision Details

Type of Revision	Summary of Changes	Date
Selected Revision	No criteria changes.	12/15/2024
Annual Revision	**Policy Title:** **Updated** from "Rufinamide" to "Antiseizure Medications-Rufinamide".	11/15/2025

	Added Preferred Product Criteria for Individual and Family Plans. Throughout the criteria, reference to antiepileptic drugs was changed to antiseizure medications.	
Annual Revision	**Lennox-Gastaut Syndrome:** In initial therapy criteria, where previously stated "patient has tried and/or is concomitantly receiving at least two other antiseizure medications", the "and/or" was updated to "or" (the "and" is redundant). Additionally, under examples of other antiseizure medications, Fycompa was updated to perampanel to reflect generic availability. **Treatment-Refractory Seizures/Epilepsy:** In initial therapy criteria, where previously stated "patient has tried and/or is concomitantly receiving at least two other antiseizure medications", the "and/or" was updated to "or" (the "and" is redundant). Additionally, under examples of other antiseizure medications, Fycompa was updated to perampanel to reflect generic availability.	5/1/2026

The policy effective date is in force until updated or retired.