Clinical Policy: Rufinamide (Banzel)

Reference Number: IL.PMN.157
Effective Date: 1.1.20
Last Review Date: 7.24.23
Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Rufinamide (Banzel®) is a triazole derivative.

FDA Approved Indication(s)

Banzel is indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in pediatric patients 1 year of age and older, and in adults.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Banzel is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Lennox-Gastaut Syndrome (must meet all)**:**

1. Diagnosis of LGS;
2. Age ≥ 1 year;
3. Dose does not exceed 3,200 mg (8 tablets or 80 mLs) per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Lennox-Gastaut Syndrome (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Banzel for Lennox-Gastaut syndrome and has received

this medication for at least 30 days;
2. Member is responding positively to therapy;

3. If request is for a dose increase, new dose does not exceed 3,200 mg (8 tablets or 80 mLs) per day.
Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

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III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
LGS: Lennox-Gastaut syndrome

Appendix B: Contraindications / Boxed Warnings
- Contraindication(s): Banzel is contraindicated in patients with familial short QT syndrome.
- Boxed warning(s): None reported

Appendix C: Contraindications / Boxed Warnings
- Contraindication(s): familial short QT syndrome
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose

LGS	*Pediatric patients 1 year to less than 17 years:* Starting daily dose: 10 mg/kg per day in two equally divided doses; increase by 10 mg/kg increments every other day to maximum dose of 45 mg/kg per day, not to exceed 3200 mg per day, in two divided doses *Adults (17 years and older):* Starting daily dose: 400-800 mg per day in two equally divided doses; increase by 400-800 mg every other day until a maximum dose of 3200 mg per day, in two divided doses, is reached	3200 mg/day

VI. Product Availability

- Film-coated tablets: 200 mg, 400 mg
- Oral suspension: 40 mg/mL

VII. References

1. Banzel Prescribing Information. Woodcliff Lake, NJ: Eisai Inc.; December 2021. Available at: https://www.banzel.com/. Accessed April 19, 2023.
2. Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs I: Treatment of new-onset epilepsy. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Epilepsy Society. July 10, 2018;91(2):74-81.
3. Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs II: Treatment resistant epilepsy. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Epilepsy Society. July 10, 2018;91(2):82-90.
4. Hancock EC, Cross JH. Treatment of Lennox-Gastaut syndrome. Cochrane Database Syst Rev. 2013 Feb 28;(2):CD003277.
5. Arzimanoglou A, French J, Blume WT, et al. Lennox-Gastaut syndrome: a consensus approach on diagnosis, assessment, management, and trial methodology. Lancet Neurol. 2009 Jan;8(1):82-93.
6. Cross JH, Auvin S, Falip M, et al. Expert opinion on the management of Lennox–Gastaut Syndrome: treatment algorithms and practical considerations. Frontiers in Neurology. 2017;8:505.
7. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com. Accessed March 16, 2021.
8. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed May 18, 2023.
9. Chin RF, Mingorance A, Ruban-Fell B, et al. Treatment guidelines for rare, early-onset, treatment-resistant epileptic conditions: a literature review on Dravet syndrome, Lennox-Gastaut syndrome and CDKL5 deficiency disorder. Frontiers in Neurology. Oct 2021;12:734612. doi: 10.3389/fneur.2021.734612.

Reviews, Revisions, and Approvals	Date	P&T Approval Date

New policy created, adapted CP.PMN.157 Rufinamide (Banzel) policy.	12.10.19	1.7.20
3Q 2021 Annual Review: added clonazepam, lamotrigine, topiramate to failure of two preferred alternatives for LGS; added 8 tablets or 80 mLs to max dosage; reviewed and updated references;	7.2.21	
added requirement for generic formulation where available	9.8.21	
4Q 2022 annual review: no significant changes; references reviewed and updated	11.17.22	
3Q2023 Annual review: requirement to use generic removed per HFS criteria. Template changes applied to other diagnoses/indications, no significant changes, references reviewed and updated.	7.24.23	
1Q2024 annual review: removed t/f criteria per HFS policy	2.19.24	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise

professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.