Clinical Policy: Rufinamide (Banzel)

Reference Number: CP.PMN.157
Effective Date: 12.01.14
Last Review Date: 08.22
Line of Business: HIM, 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 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. Prescribed by or in consultation with a neurologist;
3. Age ≥ 1 year;
4. Failure of two preferred alternatives for LGS (*see Appendix B for examples*) unless all are contraindicated or clinically significant adverse effects are experienced;
5. For brand name Banzel requests, member must use generic rufinamide, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed 3,200 mg (8 tablets or 80 mLs) per day.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): 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. For brand name Banzel requests, member must use generic rufinamide, if available, unless contraindicated or clinically significant adverse effects are experienced;
4. 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. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid.

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 – HIM.PA.154 for health insurance marketplace and 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: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Class	Examples	Dose Limit/ Maximum Dose
topiramate (Topamax®, Qudexy® XR)	• Adults and Adolescents 17 years and older: Initial dose is 25 to 50 mg/day orally. Maintenance dose is 200 to 400 mg/day orally (divided and given twice daily). • Children and Adolescents 2 to 16 years: Initial dose is 1 to 3 mg/kg/day (max: 25 mg/day) orally once daily in the evening. Maintenance dose is 5 to 9 mg/kg/day orally.	Age ≥ 17: 400 mg/day Age 2 – 16: 25 mg/day
lamotrigine (Lamictal® CD, ODT, XR)	• Patients receiving enzyme-inducing AEDs (e.g., carbamazepine, phenobarbital, phenytoin, primidone) NOT to include valproate:	With valproate: 100 mg/day With enzyme-inducing drugs: 400 mg/day

Drug Class	Examples	Dose Limit/ Maximum Dose
	○ Adults and Adolescents: Initial dose is 50 mg orally daily. Maintenance dose is 300 to 500 mg/day orally given in 2 divided doses. ○ Children 2 to 12 years: Initial dose is 0.6 mg/kg/day orally in 2 divided doses. Maintenance dose is 5 to 15 mg/kg/day (max 400 mg/day) orally given in 2 divided doses. • Patients receiving valproate: ○ Adults and Adolescents: Initial dose is 25 mg orally every other day is given for 2 weeks. Maintenance dose is 100 to 400 mg/day orally, given in 1 to 2 divided doses. ○ Children 2 to 12 years: Dosage depends on weight.	
felbamate (Felbatol®)	Adolescents and Children 2 - 14 years: Add felbamate at 15 mg/kg/day orally in 3-4 divided doses while reducing doses of other AEDs by 20-30%. Increase felbamate dose by 15 mg/kg/day increments at weekly intervals to 45 mg/kg/day orally. Max dose is 3,600 mg/day orally.	3,600 mg/day
clobazam (Sympazan®, Onfi®)	For Adults, Adolescents, & Children older than 2 years: • Patients weighing > 30 kg: Initial dose is 5 mg orally twice daily. Max dose is 20 mg orally twice daily. Dosing should be individualized based upon efficacy and tolerability. • Patients weighing ≤ 30 kg: Initial dose is 5 mg orally once daily. Max dose is 10 mg orally twice daily. Dosing should be individualized based upon efficacy and tolerability.	LGS: ≤ 30 kg: 0.2 mg/kg/day > 30 kg: 20 mg/day
clonazepam (Klonopin®)	For Adults, Adolescents, & Children: • Patients weighing > 30 kg: Initial dose is 1.5 mg/day orally, given in three equally divided doses. Max dose is 20 mg/day orally, given in three equally divided doses. • Patients weighing ≤ 30 kg: Initial dose is 0.01 to 0.03 mg/kg/day orally, given in three equally divided doses. Max dose is 0.1	≤ 30 kg: 0.2 mg/kg/day > 30 kg: 20 mg/day

Drug Class	Examples	Dose Limit/ Maximum Dose
	to 0.2 mg/kg/day orally, given in three equally divided doses.	
valproic acid (Depakene®), divalproex sodium (Depakote®)‡	Initial dose is 7 to 10 mg/kg/day PO, given three to four times daily for nonenteric-coated capsules or syrup, BID for delayed-release tablets, and QD for the extended release preparation. A typical adult starting dose is 500 mg QD. The max dose is 60 mg/kg/day or 3,000 mg/day.	60 mg/kg/day or 3,000 mg/day
levetiracetam (Spritam®, Keppra®)‡	Initial dose is 5 mg/kg/day PO, given in two or three equal doses per day. Max dose is 20 to 80 mg/kg/day PO, according to effectiveness and tolerability.	80 mg/kg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
‡ *Off-label*

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/day PO in two equally divided doses; increase by 10 mg/kg increments every other day to maximum dose of 45 mg/kg/day, not to exceed 3,200 mg/day, in two divided doses *Adults (17 years and older):* Starting daily dose: 400-800 mg/day PO in two equally divided doses; increase by 400-800 mg every other day until a maximum dose of 3,200 mg per day, in two divided doses, is reached	3,200 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 May 12, 2022.

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 May 12, 2022.
8. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed May 12, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2018 annual review: new policy for Medicaid line of business; added age requirement; references reviewed and updated.	04.06.18	08.18
3Q 2019 annual review: no significant changes; references reviewed and updated.	05.19.19	08.19
3Q 2020 annual review: no significant changes; references reviewed and updated.	05.04.20	08.20
3Q 2021 annual review: no significant changes; for brand name Banzel requests, added requirement for generic formulation where available; revised HIM.PHAR.21 to HIM.PA.154; references reviewed and updated.	03.16.21	08.21
Per November SDC, removed reference to Trokendi XR in Appendix B.	11.30.21	02.22
3Q 2022 annual review: no significant changes; references reviewed and updated.	05.12.22	08.22

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.