Clinical Policy: Rufinamide (Banzel)

Reference Number: ERX.NPA.156
Effective Date: 09.01.21
Last Review Date: 08.21
Line of Business: Commercial, 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 mL) per day.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Banzel for a covered indication 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 mL) per day.

Approval duration: 12 months

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
topiramate (Topamax®, Trokendi® XR, 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: ○ 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.	With valproate: 100 mg/day With enzyme-inducing drugs: 400 mg/day
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	3,600 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	mg/kg/day orally. Max dose is 3,600 mg/day orally.	
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 to 0.2 mg/kg/day orally, given in three equally divided doses.	≤ 30 kg: 0.2 mg/kg/day > 30 kg: 20 mg/day
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 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 3,200 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	3,200 mg/day

Indication	Dosing Regimen	Maximum Dose
	every other day until a maximum dose of 3,200 mg per day, in two divided doses, is reached	

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.; April 2020. Available at: https://www.banzel.com/. Accessed March 16, 2021.
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.
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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 March 16, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	03.16.21	08.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.