Clinical Policy: Rufinamide (Banzel)

Reference Number: PA.CP.PMN.157
Effective Date: 10.17.18
Last Review Date: 07/17/19

Revision Log

Description
Rufinamide (Banzel®) is a triazole derivative structurally unrelated to currently marketed antiepileptic drugs.

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 PA Health & Wellness® that Banzel is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Lennox-Gastaut Syndrome (must meet 1 through 5, or 6)**:**

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; and
5. Dose does not exceed 3200 mg per day; or
6. Member is currently receiving Banzel and responding positively to therapy.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 3200 mg per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

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 – PA.CP.PMN.53.

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
Anticonvulsants for LGS	clonazepam (Klonopin®), felbamate (Felbatol®), lamotrigine (Lamictal®), topiramate (Topamax®), valproic acid (Depakene®), divalproex sodium (Depakote®)	Varies according to the agent used

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.

Appendix C: Contraindications
- Banzel is contraindicated in patients with familial short QT syndrome.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
LGS	Pediatric patients 1 year and older: 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: 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.; June 2015. Available at: https://www.banzel.com/. Accessed April 6, 2018.
2. French JA, Kanner AM, Bautista J, et al. Efficacy and tolerability of the new antiepileptic drugs II: Treatment of refractory epilepsy. Report of the Therapeutics and Technology Assessment Subcommittee and Quality Standards Subcommittee of the American Academy of Neurology and the American Epilepsy Society. Neurology. 2004 Apr 27;62(8):1261-73.
3. Hancock EC, Cross JH. Treatment of Lennox-Gastaut syndrome. Cochrane Database Syst Rev. 2013 Feb 28;(2).
4. 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.
5. 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.
6. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com. Accessed April 6, 2018.
7. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed April 6, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy Created	10/18	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	