PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

BANZEL
(rufinamide)

Status: CVS Caremark Criteria ***Ref# 863-A***
Type: Initial Prior Authorization ***Ref# 496-A***

** Drugs that are listed in the target drug box include both brand and generic and all dosages forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS

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

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome in a patient one year of age or older

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Banzel is indicated for adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome in pediatric patients 1 year of age and older and in adults.[1-3]

REFERENCES

1. Banzel [package insert]. Woodcliff Lake, NJ: Eisai Inc.; April 2020.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2021; Accessed May 12, 2021.
3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed May 12, 2021.

Written by:	UM Development (SE)
Date Written:	12/2009
Revised:	(KD) 04/2010 (CAS Adapted); (CY) 03/2011 (Added Banzel Susp/Banzel MDC-1 06-2010(2)); (JK) 06/2011, (TM) 06/2012. (PL) 10/2012 (MDC-2); (MS) 05/2013, 10/2013; (GS/CF) 05/2014; (CF) 05/2015; (KM) 05/2016 (no clinical changes), (SE) 06/2016 (created separate Med D); (SF) 05/2017; (KC) 05/2018 (combined 863-A and 4966-A), 05/2019 (removed MDC from title, no clinical changes), 05/2020 (no clinical changes); (CJH) 05/2021 (no clinical changes)
Reviewed:	Medical Affairs (WLF) 12/2009; (KP) 06/2011, 06/2012; (DC) 05/2013; (KP) 10/2013; (LMS) 05/2014; (DNC) 05/2015; (ME) 05/2017; (CHART) 05/28/2020, 05/27/2021 External Review: 02/2010, 10/2010, 10/2011, 10/2012, 10/2013, 10/2014, 10/2015, 10/2016, 10/2017, 10/2018, 10/2019, 10/2020, 08/2021

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome in a patient one year of age or older?	Yes	No

Mapping Instructions (863-A)			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Approve, 36 months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you meet all of these conditions: - You are 1 year of age or older - You have seizures associated with Lennox-Gastaut Syndrome - You are using Banzel (rufinamide) along with another seizure drug Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]

Mapping Instructions (496-A)			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Approve, 12 months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you meet all of these conditions: - You are 1 year of age or older - You have seizures associated with Lennox-Gastaut Syndrome - You are using Banzel (rufinamide) along with another seizure drug Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]