



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: clobazam, rufinamide

Page: 1 of 2

Effective Date: 4/1/2025

Last Review Date: 1/17/2025

Applies to: ☒ Florida Kids

☒ New Jersey

☒ Pennsylvania Kids

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for clobazam and rufinamide under the patient's prescription drug benefit.

Description:

FDA-approved Indications

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

Clobazam is indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in patients 2 years of age or older.

Compendial Uses

Clobazam: Seizures associated with Dravet Syndrome

Applicable Drug List:

Rufinamide

Clobazam

Policy/Guideline:

Initial Coverage Criteria:

Dravet Syndrome

Authorization may be granted when the requested drug is being prescribed for the treatment of seizures associated with Dravet syndrome when the following criteria is met:

- The request is for clobazam.

Lennox-Gastaut Syndrome

Authorization may be granted when the requested drug is being prescribed for adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome when ONE of the following criteria are met:

- The request is for rufinamide, and the following criteria is met:
 - The patient is 1 year of age or older.
- The request is for clobazam, and the following criteria is met:
 - The patient is 2 years of age or older

Continuation of Therapy:

Dravet Syndrome

Authorization may be granted when the requested drug is being prescribed for adjunctive treatment of seizures associated with Dravet syndrome when ALL the following criteria are met:

- The request is for clobazam.



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- The patient has achieved and maintained positive clinical response as evidenced by reduction in frequency or duration of seizures compared with seizure activity prior to initiation of the requested drug.

Lennox-Gastaut Syndrome

Authorization may be granted when the requested drug is being prescribed for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome when ALL the following criteria are met:

- The patient meets ONE of the following:
 - The request is for rufinamide, and the following criteria is met:
 - The patient is 1 year of age or older.
 - The request is for clobazam, and the following criteria is met:
 - The patient is 2 years of age or older.
 - The patient has achieved and maintained positive clinical response as evidenced by reduction in frequency or duration of seizures compared with seizure activity prior to initiation of the requested drug.

Approval Duration and Quantity Restrictions:

Approval: 12 months

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

References:

1. Banzel [package insert]. Nutley, NJ: Eisai Inc.; December 2022.
2. Onfi [package insert]. Deerfield, IL: Lundbeck; March 2024.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed May 15, 2024.
4. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 05/15/2024).
5. Wirrell EC, Hood V, Knupp KG, et al. International Consensus on Diagnosis and Management of Dravet Syndrome. *Epilepsia*. 2022;63(7):1761-1777.