



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: clobazam, rufinamide

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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.