



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: clobazam, rufinamide

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Effective Date: 10/6/2025

Last Review Date: 9/2025

Applies to:  Illinois  Florida  Florida Kids  
 New Jersey  Maryland  Michigan  
 Pennsylvania Kids  Virginia

### 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:



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- The request is for clobazam.
- 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. Sympazan [package insert]. Warren, NJ: Aquestive Therapeutics; March 2024.
4. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed May 2, 2025.
5. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 05/02/2025).
6. Wirrell EC, Hood V, Knupp KG, et al. International consensus on diagnosis and management of Dravet syndrome. *Epilepsia*. 2022;63(7):1761-1777.