

# Initial Prior Authorization Seizure LGS, Dravet Anticonvulsants

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Banzel	rufinamide
Onfi	clobazam
Sympazan	clobazam

## Indications

### FDA-approved Indications

#### Banzel

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.

#### Onfi

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

#### Sympazan

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

Reference number(s)
871-A

## Compendial Uses

Onfi, Sympazan: Seizures associated with Dravet syndrome<sup>4-6</sup>

## 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 Onfi (clobazam) OR Sympazan (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 Banzel (rufinamide) and the following criteria is met:
  - The patient is 1 year of age or older.
- The request is for Onfi (clobazam) OR Sympazan (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 of the following criteria are met:

- The request is for Onfi (clobazam) OR Sympazan (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 of the following criteria are met:

- The patient meets ONE of the following:

Reference number(s)
871-A

- The request is for Banzel (rufinamide) and the following criteria is met:
  - The patient is 1 year of age or older.
- The request is for Onfi (clobazam) OR Sympazan (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.

## Duration of Approval (DOA)

- 871-A: DOA: 36 months

## 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.; 2024. <https://online.lexi.com>. Accessed May 15, 2024.
5. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 05/15/2024).
6. Wirrell EC, Hood V, Knupp KG, et al. International Consensus on Diagnosis and Management of Dravet Syndrome. *Epilepsia*. 2022;63(7):1761-1777.