

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 syndrome⁴⁻⁶

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.