

Initial Prior Authorization with Quantity Limit Libervant - Valtoco

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	Dosage Form
Libervant	diazepam	buccal film
Valtoco	diazepam	nasal spray

Indications

FDA-approved Indications

Libervant

Libervant is indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 2 to 5 years of age.

Valtoco

Valtoco is indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 2 years of age and older.

Coverage Criteria

Intermittent, Stereotypic Episodes of Frequent Seizure Activity

Authorization may be granted when the requested drug is being prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from the patient's usual seizure pattern in a patient with epilepsy when ONE of the following criteria is met:

- The request is for Libervant (diazepam buccal film) and the following criteria is met:
 - The patient is 2 to 5 years of age
- The request is for Valtoco (diazepam nasal spray) and the following criteria is met:
 - The patient is 2 years of age or older

Quantity Limits Apply

Quantity Limit

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Drug	1 Month Limit	3 Month Limit
Libervant (diazepam buccal film)	10 individual pouches (5 cartons) / 25 days	30 individual pouches (15 cartons) / 75 days
Valtoco (diazepam nasal spray)	10 blister packs / 25 days	30 blister packs / 75 days

Duration of Approval (DOA)

- 3517-C: DOA: 12 months

References

1. Libervant [package insert]. Warren, NJ: Aquestive Therapeutics; April 2024.
2. Valtoco [package insert]. San Diego, CA: Neurelis, Inc.; April 2025.
3. Lexicomp Online, Lexi-Drugs. 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).