

**LIBERVANT  
(diazepam buccal film)****RATIONALE FOR INCLUSION IN PA PROGRAM****Background**

Libervant (diazepam) is a benzodiazepine. Libervant's mechanism of action is not fully understood but is thought to involve potentiation of GABAergic neurotransmission resulting from binding at the benzodiazepine site of the GABA<sub>A</sub> receptor (1).

**Regulatory Status**

FDA-approved indication: 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 (1).

Libervant has a boxed warning regarding the concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death. Because of these risks, reserve concomitant prescribing of benzodiazepines and opioids for use in patients for whom alternative treatment options are inadequate and dosages and durations should be limited to the minimum required. Patients should be monitored for signs and symptoms of respiratory depression and sedation (1).

Libervant should be limited to 2 doses to treat a single episode. Libervant should be used to treat no more than one episode every five days and treat no more than five episodes per month (1).

Benzodiazepines, including Libervant, can increase intraocular pressure in patients with glaucoma. Libervant may be used in patients with open-angle glaucoma only if they are receiving appropriate therapy. Libervant is contraindicated in patients with acute-narrow angle glaucoma (1).

Antiepileptic drugs (AEDs), including Libervant, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior (1).

The safety and effectiveness of Libervant in pediatric patients less than 2 years of age and greater than 5 years of age have not been established (1).



**BlueCross  
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Federal Employee Program.

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### **Summary**

Libervant (diazepam) is a benzodiazepine. Libervant's mechanism of action is not fully understood but is thought to involve potentiation of GABAergic neurotransmission resulting from binding at the benzodiazepine site of the GABA<sub>A</sub> receptor. The safety and effectiveness of Libervant in pediatric patients less than 2 years of age and greater than 5 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Libervant while maintaining optimal therapeutic outcomes.

### **References**

1. Libervant [package insert]. Warren, NJ: Aquestive Therapeutics; April 2024.