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Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Central Nervous System Drugs	**Original Policy Date:**	May 31, 2024
Subject:	Libervant	**Page:**	1 of 5

Last Review Date: December 13, 2024

Libervant

Description

Libervant (diazepam buccal film)

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 $GABA_A$ 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).

Related policies
Nayzilam, Valtoco

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Libervant may be considered **medically necessary** if the conditions indicated below are met.

Libervant may be considered **investigational** for all other indications.

Prior-Approval Requirements

Patients 2 to 5 years of age with a paid claim for a seizure medication such as: divalproex sodium (Depakote, Depakote ER), lamotrigine (Lamictal), levetiracetam (Keppra), topiramate (Topamax) in the past 180 days are exempt from these initial PA requirements

Age 2 to 5 years of age

Diagnosis

Patient must have the following:
Intermittent seizure episodes (i.e., seizure clusters, acute repetitive seizures)

AND ALL of the following:

a. Medication will be used for acute seizures
b. Episodes are distinct from the patient's usual epilepsy seizure pattern
c. Patient is on a stable regimen of antiepileptic therapy
d. Prescriber agrees to assess the patient before prescribing concomitant opioid therapy to limit opioid dosages and durations to the minimum required
e. **NOT** being used for the treatment of anxiety
f. **NO** concurrent therapy with another Prior Authorization (PA) benzodiazepine (see Appendix 1)

Prior–Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Quantity 10 doses per 30 days

Duration 3 months

Prior–Approval *Renewal* Limits

Quantity 10 doses per 30 days

Duration 6 months

Rationale

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 $GABA_A$ 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.

Policy History

Date	Action
May 2024	Addition to PA
September 2024	Annual review
December 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.

Appendix 1 - List of Prior Authorization (PA) Benzodiazepines

Generic Name	Brand Name
diazepam	Libervant
diazepam	Valtoco
midazolam	Nayzilam