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Federal Employee Program.

## **VALTOCO (diazepam nasal spray)**

### **RATIONALE FOR INCLUSION IN PA PROGRAM**

#### **Background**

Valtoco (diazepam) is a benzodiazepine. Valtoco'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: Valtoco is a benzodiazepine 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. (1).

Valtoco 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 (1).

Valtoco should be limited to 2 doses to treat a single episode. Valtoco 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 Valtoco, can increase intraocular pressure in patients with glaucoma. Valtoco may be used in patients with open-angle glaucoma only if they are receiving appropriate therapy. Valtoco is contraindicated in patients with narrow-angle glaucoma (1).

Antiepileptic drugs (AEDs), including Valtoco, 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 Valtoco in pediatric patients less than 2 years of age have not been established (1).



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### **Summary**

Valtoco (diazepam) is a benzodiazepine. Valtoco'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 Valtoco in pediatric patients less than 2 years of age have not been established (1).

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

### **References**

1. Valtoco [package insert]. San Diego, CA: Neurelis, Inc.; April 2025.