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Prior Authorization Antiseizure Medications – Valtoco® (diazepam nasal spray)

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Product Identifier(s)

Effective 1/1/23 to 2/6/23: 106884

Effective 2/7/23: 79950

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

Cigna covers diazepam nasal spray (Valtoco®) as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:

Prior Authorization is recommended for prescription benefit coverage of Valtoco. All approvals are provided for the duration noted below.

FDA Indication(s)

- Intermittent Episodes of Frequent Seizure Activity (i.e., seizure clusters, acute repetitive seizures).**
Approve for 1 year if the individual meets the following criteria (A and B):
 - Individual is currently receiving maintenance antiseizure medication(s); AND
 - The medication is prescribed by or in consultation with a neurologist.

Conditions Not Covered

Diazepam nasal spray (Valtoco) is considered experimental, investigational or unproven for ANY other use.

Background

Overview

Valtoco, a benzodiazepine, 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 ≥ 6 years of age.¹

Valtoco is for acute treatment only. Do not use more than two doses of Valtoco to treat a single episode.¹ It is recommended that Valtoco be used to treat no more than one episode every 5 days and no more than five episodes per month.

Disease Overview

Patients with epilepsy can experience acute repetitive seizures or seizure clusters.² Patients with severe and/or poorly controlled epilepsy are more likely to experience seizure clusters. Seizure clusters can result in increased emergency room visits or hospitalization, and they can disrupt the daily life, studies, and work of patients and caregivers. They are particularly concerning because of their association with status epilepticus, a potentially life-threatening condition. Benzodiazepine rescue medication is the primary acute therapy for management of seizure clusters, helping to abort clusters and reduce emergency department visits.

References

1. Valtoco® nasal spray [prescribing information]. San Diego, CA: Neurelis; January 2023.
2. Jafarpour S, Hirsch LJ, Gainza-Lein M, et al. Seizure cluster: Definition, prevalence, consequences, and management. *Seizure*. 2019;68:9-15.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	The policy name was changed from Antiepileptics – Valtoco to Antiseizure Medications – Valtoco. Intermittent Episodes of Frequent Seizure Activity (i.e., seizure clusters, acute repetitive seizures): The term antiepileptic medications was changed to antiseizure medications.	02/15/2023

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