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Diazepam Nasal Spray

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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.

Overview

This policy supports medical necessity review for Valtoco® (diazepam) nasal spray.

Medical Necessity Criteria

Diazepam nasal spray (Valtoco) is considered medically necessary when the following are met:

- 1. Intermittent Episodes of Frequent Seizure Activity (for example, seizure clusters, acute repetitive seizures) Individual meets ALL of the following criteria:
A. Age 6 years or older
B. Documentation of use for the acute treatment of seizure activity
C. Documentation of currently receiving maintenance antiepileptic medication(s)
D. Medication is prescribed by, or in consultation with, a neurologist

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Note: Receipt of sample product does not satisfy any criteria requirements for coverage.

Reauthorization Criteria

Continuation of Valtoco is considered medically necessary for the treatment of intermittent episodes of frequent seizure activity when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months.

Reauthorization approval duration: up to 12 months.

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 \geq 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; February 2021.
2. Jafarpour S, Hirsch LJ, Gaínza-Lein M, et al. Seizure cluster: Definition, prevalence, consequences, and management. *Seizure*. 2019; 68:9-15.

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