Drug Coverage Policy

Effective Date.....5/15/2025
Coverage Policy Number.....IP0105
Policy Title.....Valtoco

Antiseizure Medications – Valtoco

- Valtoco® (diazepam nasal spray – Neurelis)

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. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. 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
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.

Coverage Policy

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

Valtoco is considered medically necessary when the following criteria are met:

FDA-Approved Indication

1. **Intermittent Episodes of Frequent Seizure Activity (i.e., seizure clusters, acute repetitive seizures).** Approve for 1 year if the patient meets the following (A B, and C):
   A) Patient is currently receiving maintenance antiseizure medication(s); AND
   B) The medication is prescribed by or in consultation with a neurologist; AND
   C) Preferred product criteria is met for the product as listed in the below table

Individual and Family Plans:

Product	Criteria
Valtoco (diazepam nasal spray)	**ONE** of the following: 1. Patient has tried Nayzilam [may require prior authorization] 2. Patient is < 12 years of age 3. Patient has previously received Valtoco OR is currently receiving Valtoco

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.

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

Valtoco for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

References

1. Valtoco® nasal spray [prescribing information]. San Diego, CA: Neurelis; January 2023.

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

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**Intermittent Episodes of Frequent Seizure Activity:** Removed age-related requirement criterion. Removed criterion pertaining to use for acute treatment of seizure activity	06/01/2024
Annual Revision	**Preferred Product Table:** **Added** preferred product requirement criteria for Valtoco for Individual and Family Plans.	5/15/2025

The policy effective date is in force until updated or retired.