MEDICAL MUTUAL®

Drug Policy

Policy: SD	Valtoco (diazepam nasal spray)	Annual Review Date: 02/20/2025 Last Revised Date: 02/20/2025

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.

POLICY STATEMENT

This policy involves the use of Valtoco. Prior authorization is recommended for pharmacy benefit coverage of Valtoco. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Valtoco as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Valtoco be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for the duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Valtoco is recommended in those who meet the following criteria:

1. **Intermittent Episodes of Frequent Seizure Activity (i.e., seizure clusters, acute repetitive seizures)**
   Criteria. *Patient must meet the following criteria (A and B)*
   - **A.** Patient is currently receiving maintenance antiseizure medication(s); AND
   - **B.** Valtoco is prescribed by or in consultation with a neurologist.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days
B) *Extended Approval:* 365 days

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CONDITIONS NOT RECOMMENDED FOR APPROVAL

Valtoco has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Valtoco® nasal spray [prescribing information]. San Diego, CA: Neurelis, Inc.; January 2020.
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6. Data on file. Clinical and economic evidence supporting formulary consideration of Valtoco® CIV (Midazolam Nasal Spray) for seizure clusters. UCB, Inc.; June 24, 2019.
7. diazepam. In: DRUGDEX [online database]. Truven Health Analytics. Greenwood Village, CO. Last updated 19 September 2019. Accessed 10 October 2019.