MEDICAL MUTUAL®

Drug Policy

Policy:	**Nayzilam Prior Authorization Policy** Nayzilam (midazolam nasal spray-UCB)	**Annual Review Date:** **10/17/2024** **Last Revised Date:** **10/17/2024**

OVERVIEW

Nayzilam, 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 ≥ 12 years of age.[1]

POLICY STATEMENT

This policy involves the use of Nayzilam. Prior authorization is recommended for pharmacy benefit coverage of Nayzilam. 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 Nayzilam as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Nayzilam be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Nayzilam 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.** Nayzilam is prescribed by or in consultation with a neurologist; AND
   - **C.** The patient is at least 12 years of age.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 2 years
B) *Extended Approval:* 2 years

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CONDITIONS NOT RECOMMENDED FOR APPROVAL

Nayzilam 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. Nayzilam® nasal spray [prescribing information]. Smyrna, GA: UCB; January 2023.
2. Jafarpour S, Hirsch LJ, Gaínza-Lein M, et al. Seizure cluster: Definition, prevalence, consequences, and management. *Seizure*. 2019;68:9-15.
3. Chung S, Szaflarski JP, Choi EJ, et al. A systematic review of seizure clusters: Prevalence, risk factors, burden of disease and treatment patterns. *Epilepsy Res*. 2021;177:106748.