

PRIOR AUTHORIZATION POLICY

POLICY: Antiepileptics – Nayzilam Prior Authorization Policy

- Nayzilam® (midazolam nasal spray – UCB)

REVIEW DATE: 09/14/2022

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

Disease Overview

Patients with epilepsy can experience acute repetitive seizures or seizure clusters.² Seizure clusters are estimated to occur in approximately 15% of adults with uncontrolled epilepsy.³ No consensus definition of a seizure cluster has been agreed upon, and seizure cluster is not listed in the International League Against Epilepsy commission on classification and terminology.² A broad definition of seizure clusters has been proposed to be “acute episodes of deterioration in seizure control”. More specifically, they could be defined as a series of grouped seizures that have short interictal periods. However, the number of seizures and the interictal period are the subject of controversy. 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.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Nayzilam. 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 efficacy, approval requires Nayzilam to 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

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 criteria (A and B):
 - A) Patient is currently receiving maintenance antiepileptic medication(s); AND
 - B) Nayzilam is prescribed by or in consultation with a neurologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

09/14/2022

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Coverage of Nayzilam is not recommended in the following situations:

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

REFERENCES

1. Nayzilam® nasal spray [prescribing information]. Smyrna, GA: UCB; February 2021.
2. Jafarpour S, Hirsch LJ, Gaínza-Lein M, et al. Seizure cluster: Definition, prevalence, consequences, and management. *Seizure*. 2019;68:9-15.
3. Chen Z, Brodie MJ, Liew D, et al. Treatment outcomes in patients with newly diagnosed epilepsy treated with established and new antiepileptic drugs: a 30-year longitudinal cohort study. *JAMA Neurol*. 2018;75(3):279-286.