PRIOR AUTHORIZATION POLICY

POLICY: Antiseizure Medications – Nayzilam Prior Authorization Policy
- Nayzilam® (midazolam nasal spray – UCB)

REVIEW DATE: 09/18/2024

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 AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

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] No consensus definition of a seizure cluster has been agreed upon.[3] 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. All approvals are provided for the duration noted below. 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.

- **Nayzilam® (midazolam nasal spray – UCB)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 BOTH of the following (A and B):
   A) Patient is currently receiving maintenance antiseizure medication(s); AND
   B) The medication is prescribed by or in consultation with a neurologist.

CONDITIONS NOT COVERED

- **Nayzilam® (midazolam nasal spray – UCB)**

is(are) considered experimental, investigational, or unproven for ANY other use(s).

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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	The policy name was changed from Antiepileptics – Nayzilam Prior Authorization Policy to Antiseizure Medications – Nayzilam Prior Authorization Policy. In the criteria, reference to antiepileptic medications was changed to antiseizure medications.	09/20/2023
Annual Revision	No criteria changes.	09/18/2024