UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Nayzilam and Valtoco

Program	Prior Authorization
Medication	Nayzilam (midazolam) and Valtoco (diazepam)
Markets in Scope	Arizona, California, Hawaii, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	4/2020
P&T Approval Date	4/2020
Effective Date	7/2020

1. Background

Nayzilam and Valtoco are benzodiazepines 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. Nayzilam is indicated for patients 12 years of age and older. Valtoco is indicated for patients 6 years of age and older.

2. Coverage Criteria:

A. Nayzilam

1. Initial Authorization

a. **Nayzilam** will be approved based on **all** of the following criteria:

(1) Diagnosis of epilepsy

-AND-

(2) Nayzilam is being prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity that are distinct from a patient's usual seizure pattern

-AND-

(3) The prescriber provides a reason or special circumstance that precludes the use of diazepam rectal gel

Authorization of therapy will be issued for 12 months.

2. Reauthorization

a. **Nayzilam** will be approved based on the following criterion:

(1) Documentation of positive clinical response to therapy

Authorization of therapy will be issued for 12 months.

B. Valtoco

1. Initial Authorization

a. **Valtoco** will be approved based on **all** of the following criteria:

(1) Diagnosis of epilepsy

-AND-

(2) Valtoco is being prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity that are distinct from a patient's usual seizure pattern

-AND-

(3) The prescriber provides a reason or special circumstance that precludes the use of diazepam rectal gel

-AND-

(4) One of the following:
(a) Patient is less than 12 years of age

-OR-

(b) History of failure, contraindication, or intolerance to Nayzilam

Authorization of therapy will be issued for 12 months.

2. Reauthorization

a. **Valtoco** will be approved based on the following criterion:

(1) Documentation of positive clinical response to therapy

Authorization of therapy will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes

(ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

- Prior Authorization/Notification may also be in place.

4. References:

1. Nayzilam [package insert]. Smyrna, GA: UCB, Inc.; 2019.
2. Valtoco [package insert]. San Diego, CA: Neurelis, Inc.; 2020.

Program	Prior Authorization – Nayzilam, Valtoco
Change Control	
Date	Change
4/2020	New Program