Nayzilam (midazolam nasal spray)
Valtoco (diazepam nasal spray)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Nayzilam 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 and older.

Valtoco 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 and older.

POLICY

Criteria for Approval

I. Nayzilam will be covered with prior authorization when the following criteria are met:
   - The requested drug is being prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from the patient's usual seizure pattern in a patient with epilepsy

   AND
   - The patient is 12 years of age or older

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Approval will be for **12 months.**

II. Valtoco will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from the patient's usual seizure pattern in a patient with epilepsy

AND

- The patient is 6 years of age or older

Approval will be for **12 months.**

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Nayzilam - 10 nasal spray units per 30 days
Valtoco - 5 cartons (10 blister packs) per 30 days

CLINICAL RATIONALE

Nayzilam 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 and older. Patients and caregivers should be instructed on what is and is not an intermittent and stereotypic episode of increased seizure activity (i.e., seizure cluster) that is appropriate for treatment, and the timing of administration in relation to the onset of the episode. The initial dose of Nayzilam is one spray (5 mg dose) administered into one nostril. If needed, one additional spray (5 mg dose) may be administered into the opposite nostril after 10 minutes if the patient has not responded to the initial dose. A second dose of Nayzilam should not be administered if the patient has trouble breathing or if there is excessive sedation that is uncharacteristic of the patient during a seizure cluster episode. Do not use more than 2 doses of Nayzilam to treat a single episode. It is recommended that Nayzilam be used to treat no more than 1 episode every three days and no more than 5 episodes per month.

Nayzilam is supplied as a solution of midazolam. Each single-dose nasal spray unit delivers 5 mg of midazolam in 0.1 mL of solution. Nayzilam is supplied in boxes of 2 nasal spray units, each contained within an individual blister pack. Because it is not recommended to treat more than 5 episodes per month and each episode could require up to 2 doses, the limit will be set at 5 boxes, 10 nasal spray units.

Valtoco 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 and older. Prior to treatment, healthcare professionals should instruct the individual administering Valtoco on how to identify seizure clusters and use the product appropriately. The recommended dose of Valtoco nasal spray is 0.2mg/kg or 0.3mg/kg, depending on the patient's age and weight. A second dose of Valtoco, when required, may be administered at least 4 hours after the initial dose. If the second dose is to be administered, use a new blister pack of Valtoco. Do not use more than 3 doses of Valtoco to treat a single episode. It is recommended that Valtoco be used to treat no more than one episode every five days and no more than five episodes per month.

Recommended Valtoco Dosage for Adults and Pediatric Patients 6 Years of Age and Older

Dose Based on Age and Weight	Administration

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6 to 11 Years of Age (0.3 mg/kg)	12 Years of Age and Older (0.2 mg/kg)	Dose (mg)	Number of Nasal Spray Devices	Number of Sprays
Weight (kg)	**Weight (kg)**			
10 to 18	14 to 27	5	One 5 mg device	One spray in one nostril
19 to 37	28 to 50	10	One 10 mg device	One spray in one nostril
38 to 55	51 to 75	15	Two 7.5 mg devices	One spray in each nostril
56 to 74	76 and up	20	Two 10 mg devices	One spray in each nostril

Valtoco is available in 5 mg, 7.5 mg, and 10 mg strengths. Valtoco is supplied and packed in doses of 5 mg, 10 mg, 15 mg, or 20 mg cartons, each containing 2 individual blister packs. Each blister pack contains enough Valtoco to administer one dose of the prescribed quantity. Each carton contains enough Valtoco to treat one to two episodes. Because it is not recommended to treat more than 5 episodes per month and each episode could require up to 2 doses, the limit will be set at 5 cartons, 10 blister packs.

Available Packaging Configurations

Description	Contents
5 mg carton	2 individual blister packs, each containing one 5 mg nasal spray device
10 mg carton	2 individual blister packs, each containing one 10 mg nasal spray device
15 mg carton	2 individual blister packs, each containing two 7.5 mg nasal spray devices
20 mg carton	2 individual blister packs, each containing two 10mg nasal spray devices

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- Code(s), if applicable

REFERENCES

- Nayzilam [package insert]. Plymouth, MN: Proximagen, LLC; February 2021.
- Valtoco [package insert]. San Diego, CA: Neurelis, Inc.; February 2021.

*Some content reprinted from CVS Health

POLICY HISTORY

Policy #: 05.03.92
Policy Creation: January 2020
Reviewed: July 2022
Revised: April 2020
Current Effective Date: May 24, 2020

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