BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Pharmacy Policy

Valtoco/Nayzilam

Policy Number: 9.226
Version Number: 1.0
Version Effective Date: 6/1/2021

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan	**Boston Medical Center HealthNet Plan**
☐ New Hampshire Medicaid	☒ MassHealth ACO ☒ MassHealth MCO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **Valtoco (diazepam) Nasal Spray**
- **Nayzilam (midazolam) Nasal Spray**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Required Medical Information	1. Diagnosis of partial or generalized epilepsy. **AND** 2. Medication is being prescribed for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity that are distinct from a patients' usual seizure pattern. **AND** 3. Prescribed by or in consultation with a neurologist. **AND** 4. Appropriate age: a. Nayzilam: Age ≥ 12 years; ***OR*** b. Valtoco: Age ≥ 6 years. **AND**

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	5. Currently on a stable regimen of antiepileptic drugs. **AND** 6. Member has completed a trial and failure, has a contraindication to, or there is other clinical rationale that precludes the use of diazepam gel. **AND** 7. Dose does not exceed 2 doses per single episode.
Reauthorization Criteria	1. Currently receiving medication via BMCHP benefit or member has previously met initial approval criteria. **AND** 2. Member has experienced a positive clinical response to therapy. **AND** 3. Dose does not exceed 2 doses per single episode.
Quantity Limit	1 box per fill
Coverage Duration	12 months

Clinical Background Information and References

1. Holsti M, Dudley N, Schunk, J et. al. Intranasal midazolam vs rectal diazepam for the home treatment of acute seizures in pediatric patients with epilepsy. Arch Pediatr Adolesc Med. 2010 Aug;164(8):747-53.
2. Nayzilam (midazolam) [prescribing information]. Plymouth, MN: Proximagen LLC; May 2019
3. Valtoco (diazepam intranasal) [prescribing information]. San Diego, CA: Neurelis Inc; August 2020.
4. Scheepers M, Scheepers B, Clarke M, Comish S, Ibitoye M. Is intranasal midazolam an effective rescue medication in adolescents and adults with severe epilepsy? Seizure. 2000;9(6):417-422.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
2/11/2021	6/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
2/11/2021	Policy created	6/1/2021	P&T Committee

Next Review Date

2/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.