

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Anticonvulsants, Rescue Agents PDL Edit
<b>First Implementation Date:</b>	January 21, 2021
<b>Proposed Date:</b>	September 16, 2021
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

**Why Issue Selected:** There are multiple FDA approved agents for the treatment of acute repetitive seizures or clusters. Diazepam rectal (Diastat®) is indicated for the management of select, refractory participants 2 years of age or older with epilepsy on stable regimens of antiepileptic drugs, who require intermittent use of diazepam to control episodes of increased seizure activity. Diazepam intranasal (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 usual seizure pattern in epilepsy participants 6 years of age or older. Lastly, midazolam intranasal (Nayzilam®) is indicated for acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from usual seizure pattern in epilepsy participants 12 years of age or older. All three agents carry the same contraindication of acute narrow-angle glaucoma. Clinical guidelines from both the American Epilepsy Society and Neurocritical Care Society recommend diazepam rectal and midazolam intranasal when parenteral benzodiazepines are not available. These guidelines were also published prior to the approval of diazepam intranasal therefore, this agent lacks guideline recommendations.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	<ul style="list-style-type: none"> <li>• Diastat®</li> <li>• Diazepam Rectal</li> <li>• Valtoco®</li> </ul>	<ul style="list-style-type: none"> <li>• Nayzilam®</li> </ul>

- Type of Criteria:**     Increased risk of ADE                       Preferred Drug List  
                                   Appropriate Indications                       Clinical Edit
- Data Sources:**        Only Administrative Databases                       Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Anticonvulsants, Rescue Agents
- Age range: All appropriate MO HealthNet participants

## Approval Criteria

- Documented diagnosis of seizure disorder **AND**
- ~~For diazepam rectal: participants aged 2 years and older AND~~
- ~~For Nayzilam: participants aged 12 years and older AND~~
- Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents
  - Documented trial period for preferred agents OR
  - Documented ADE/ADR to preferred agents OR
- ~~For Valtoco:~~
  - ~~Participants aged 6 years and older AND~~
  - ~~Documented therapeutic trial on generic diazepam rectal~~

## Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met

## Required Documentation

Laboratory Results:   
MedWatch Form:

Progress Notes:   
Other:

## Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)  
Rule Type: PDL

## Default Approval Period

1 year

## References

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3. Diastat [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; March 2021.
4. Nayzilam [package insert]. Smyrna, GA: UCB, Inc.; February 2021.
5. Brophy GM, Bell R, Claassen J; Neurocritical Care Society Status Epilepticus Guideline Writing Committee. Guidelines for the evaluation and management of status epilepticus. *Neurocrit Care.* 2012;17(1):3-23. doi: 10.1007/s12028-012-9695-z.
6. Glauser T, Shinnar S, Gloss D, et al. Evidence-based guideline: treatment of convulsive status epilepticus in children and adults: report of the Guideline Committee of the American Epilepsy Society. *Epilepsy Curr.* 2016;16(1):48-61. doi: 10.5698/1535-7597-16.1.48

*SmartPA PDL Proposal Form*

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8. Bhattacharyya M, Kalra V, Gulati S. Intranasal midazolam vs rectal diazepam in acute childhood seizures. *Pediatr Neurol.* 2006;34(5):355-359. doi: 10.1016/j.pediatrneurol.2005.09.006
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