

SmartPA Criteria Proposal

Drug/Drug Class:	Anticonvulsants, Rescue Agents PDL Edit
First Implementation Date:	TBD
Proposed Date:	September 17, 2020
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	<input type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input checked="" 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"> • Diazepam Rectal • Valtoco® 	<ul style="list-style-type: none"> • Diastat® • Nayzilam®

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 aged 2 years or older

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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 no approval criteria are 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

1. Evidence-Based Medicine and Fiscal Analysis: "Anticonvulsants: Rescue Agents Therapeutic Class Review"-, Conduent Business Services, L.L.C., Richmond, VA; July 2020.
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3. Diastat [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; 2016.
4. Nayzilam [package insert]. Smyrna, GA: UCB, Inc.; 2019.
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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
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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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10. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
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