



# Nasal Antiepileptics Quantity Limit Program Summary

Quantity limits apply to FlexRx Closed, FlexRx Open, FocusRx, GenRx Closed, GenRx Open, Health Insurance Marketplace, and KeyRx.

## POLICY REVIEW CYCLE

**Effective Date**  
03-01-2024

**Date of Origin**  
04-01-2020

## FDA APPROVED INDICATIONS AND DOSAGE

See package insert for FDA prescribing information: <https://dailymed.nlm.nih.gov/dailymed/index.cfm>

## POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Nayzilam	Midazolam Nasal Spray Soln 5 MG/0.1 ML	5 MG/0.1 ML	10	Bottles	30	DAYS			
Valtoco 10 mg dose	Diazepam Nasal Spray 10 MG/0.1 ML	10 MG/0.1 ML	5	Boxes	30	DAYS			
Valtoco 15 mg dose	Diazepam Nasal Spray Ther Pack 2 x 7.5 MG/0.1ML (15 MG Dose)	7.5 MG/0.1 ML	5	Boxes	30	DAYS			
Valtoco 20 mg dose	Diazepam Nasal Spray Ther Pack 2 x 10 MG/0.1ML (20 MG Dose)	10 MG/0.1 ML	5	Boxes	30	DAYS			
Valtoco 5 mg dose	Diazepam Nasal Spray 5 MG/0.1 ML	5 MG/0.1 ML	5	Boxes	30	DAYS			

## CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Nayzilam	Midazolam Nasal Spray Soln 5 MG/0.1 ML	5 MG/0.1ML	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Valtoco 10 mg dose	Diazepam Nasal Spray 10 MG/0.1 ML	10 MG/0.1ML	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Valtoco 15 mg dose	Diazepam Nasal Spray Ther Pack 2 x 7.5 MG/0.1ML (15 MG Dose)	7.5 MG/0.1ML	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Valtoco 20 mg dose	Diazepam Nasal Spray Ther Pack 2 x 10 MG/0.1ML (20 MG Dose)	10 MG/0.1ML	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Valtoco 5 mg dose	Diazepam Nasal Spray 5 MG/0.1 ML	5 MG/0.1ML	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

## QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p><b>Quantity Limit for the Target Agent(s)</b> will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the program quantity limit <b>OR</b></li> <li>2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> <li>A. BOTH of the following: <ol style="list-style-type: none"> <li>1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. Information has been provided to support therapy with a higher dose for the requested indication <b>OR</b></li> </ol> </li> <li>B. BOTH of the following: <ol style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit <b>OR</b></li> </ol> </li> <li>C. BOTH of the following: <ol style="list-style-type: none"> <li>1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. Information has been provided to support therapy with a higher dose for the requested indication</li> </ol> </li> </ol> </li> </ol> <p><b>Length of Approval:</b> up to 12 months</p>