



# Duvyzat Prior Authorization with Quantity Limit Program Summary

## POLICY REVIEW CYCLE

**Effective Date**  
11-01-2025

**Date of Origin**  
08-15-2024

## POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Duvyzat	givinostat hcl oral susp	8.86 MG/ML	M ; N ; O ; Y	N		

## 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
Duvyzat	givinostat	8.86 MG/ML	3	Bottles	30	DAYS			

## CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Duvyzat	givinostat hcl oral susp	8.86 MG/ML	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

## CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Duvyzat	givinostat	8.86 MG/ML	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

## PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	<p><b>Initial Evaluation</b></p> <p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>1. BOTH of the following: <ol style="list-style-type: none"> <li>A. ONE of the following: <ol style="list-style-type: none"> <li>1. BOTH of the following: <ol style="list-style-type: none"> <li>A. The patient has a diagnosis of Duchenne Muscular Dystrophy confirmed by genetic analysis (i.e., dystrophin deletion or duplication mutation) (genetic test required) <b>AND</b></li> <li>B. ONE of the following: <ol style="list-style-type: none"> <li>1. BOTH of the following: <ol style="list-style-type: none"> <li>A. The patient has been stable on corticosteroid therapy used to treat DMD for at least 6 months <b>AND</b></li> <li>B. The patient will continue to be on corticosteroid therapy for DMD while taking the requested agent <b>OR</b></li> </ol> </li> <li>2. The patient has an intolerance or hypersensitivity to a corticosteroid used to treat DMD <b>OR</b></li> <li>3. The patient has an FDA labeled contraindication to all corticosteroids used to treat DMD <b>OR</b></li> </ol> </li> <li>2. The patient has another FDA labeled indication for the requested agent and route of administration <b>AND</b></li> </ol> </li> <li>B. If the patient has an FDA labeled indication, then ONE of the following: <ol style="list-style-type: none"> <li>1. The patient's age is within FDA labeling for the requested indication for the requested agent <b>OR</b></li> <li>2. There is support for the use of the requested agent for the patient's age for the requested indication <b>AND</b></li> </ol> </li> </ol> </li> <li>2. If the requested agent is to be used to treat DMD, the patient is ambulatory <b>AND</b></li> <li>3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., pediatric neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis <b>AND</b></li> </ol> </li> </ol>

Module	Clinical Criteria for Approval
	<p data-bbox="277 180 1357 212">4. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p data-bbox="232 247 498 279"><b>Length of Approval:</b></p> <p data-bbox="232 312 483 344">BCBSOK: 36 months</p> <p data-bbox="232 378 570 409">ALL other plans: 12 months</p> <p data-bbox="232 443 1083 474">NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p data-bbox="232 571 1190 602"><b>The requested agent will also be approved when the following are met:</b></p> <ol data-bbox="277 640 1403 1104" style="list-style-type: none"> <li>1. The member resides in Ohio <b>AND</b></li> <li>2. The plan is Fully Insured or HIM Shop (SG) <b>AND</b> BOTH of the following       <ol style="list-style-type: none"> <li>A. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></li> <li>B. ONE of the following:           <ol style="list-style-type: none"> <li>1. The patient has another FDA labeled indication for the requested agent and route of administration <b>OR</b></li> <li>2. The patient has another indication that is supported in compendia for the requested agent and route of administration <b>OR</b></li> <li>3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required]</li> </ol> </li> </ol> </li> </ol> <p data-bbox="232 1142 1395 1199"><b>Non-oncology compendia allowed:</b> DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p data-bbox="232 1236 1380 1323"><b>Oncology compendia allowed:</b> NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p data-bbox="232 1360 498 1392"><b>Length of Approval:</b></p> <p data-bbox="232 1425 483 1457">BCBSOK: 36 months</p> <p data-bbox="232 1491 570 1522">ALL other plans: 12 months</p> <p data-bbox="232 1556 1083 1587">NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p data-bbox="232 1688 498 1719"><b>Renewal Evaluation</b></p> <p data-bbox="232 1753 1083 1785"><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol data-bbox="277 1822 1409 1997" style="list-style-type: none"> <li>1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [NOTE: Patients not previously approved for the requested agent will require initial evaluation review] <b>AND</b></li> <li>2. The patient has had improvements or stabilization with the requested agent (e.g., slowed disease progression, improved strength, timed motor function, pulmonary function; reduced need for scoliosis surgery) <b>AND</b></li> </ol>

Module	Clinical Criteria for Approval
	<p>3. If the requested agent is to be used to treat DMD, the patient is ambulatory <b>AND</b></p> <p>4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., pediatric neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis <b>AND</b></p> <p>5. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p><b>Length of Approval:</b></p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>

### 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 BOTH of the following: <ol style="list-style-type: none"> <li>A. The requested agent does NOT have a maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>B. There is support for therapy with a higher dose for the requested indication</li> </ol> </li> </ol> <p><b>Length of Approval:</b> 12 months</p>