



Vykat XR Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
03-15-2026

Date of Origin
05-15-2025

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Vykat xr	diazoxide choline tab er	150 MG ; 25 MG ; 75 MG	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
Vykat xr	diazoxide choline tab er	25 MG	120	Tablets	30	DAYS			
Vykat xr	diazoxide choline tab er	75 MG	210	Tablets	30	DAYS			
Vykat xr	diazoxide choline tab er	150 MG	90	Tablets	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Vykat xr	diazoxide choline tab er	150 MG ; 25 MG ; 75 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; 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
Vykat xr	diazoxide choline tab er	25 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Vykat xr	diazoxide choline tab er	150 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Vykat xr	diazoxide choline tab er	75 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Annual PY ; 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
	<p data-bbox="233 218 469 247">Initial Evaluation</p> <p data-bbox="233 285 1101 315">Target Agent(s) will be approved when ALL of the following are met:</p> <ol data-bbox="282 352 1416 814" style="list-style-type: none">1. ONE of the following:<ol data-bbox="375 380 1416 554" style="list-style-type: none">A. The patient has a diagnosis of Prader-Willi syndrome and BOTH of the following:<ol data-bbox="472 411 1416 495" style="list-style-type: none">1. The patient has hyperphagia AND2. The patient's diagnosis has been confirmed by genetic testing indicating mutation on chromosome 15 (medical records required) ORB. The patient has another FDA labeled indication for the requested agent and route of administration AND2. If the patient has an FDA labeled indication, then ONE of the following:<ol data-bbox="375 585 1416 695" style="list-style-type: none">A. The patient's age is within FDA labeling for the requested indication for the requested agent ORB. There is support for using the requested agent for the patient's age for the requested indication AND3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND4. The patient does NOT have any FDA labeled contraindications to the requested agent <p data-bbox="233 852 505 882">Length of Approval:</p> <p data-bbox="233 919 483 949">BCBSOK: 36 months</p> <p data-bbox="233 987 573 1016">ALL other plans: 12 months</p> <p data-bbox="233 1054 1101 1083">NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p data-bbox="233 1180 1268 1209">The requested agent will also be approved when ONE of the following is met:</p> <ol data-bbox="282 1247 1416 1942" style="list-style-type: none">1. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following:<ol data-bbox="375 1274 1416 1507" style="list-style-type: none">A. The patient does NOT have any FDA labeled contraindications to the requested agent ANDB. The requested indication is a rare disease ANDC. ONE of the following:<ol data-bbox="472 1392 1416 1507" style="list-style-type: none">1. The patient has another FDA labeled indication for the requested agent and route of administration OR2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR2. ALL of the following:<ol data-bbox="375 1539 1416 1942" style="list-style-type: none">A. The member resides in Ohio ANDB. The plan is Fully Insured or HIM Shop (SG) ANDC. The patient does NOT have any FDA labeled contraindications to the requested agent ANDD. ONE of the following:<ol data-bbox="472 1682 1416 1942" style="list-style-type: none">1. The patient has another FDA labeled indication for the requested agent and route of administration OR2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR3. 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

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	<p>blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required]</p> <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: 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>Length of Approval:</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> <p>Renewal Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 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) AND 2. The patient has had clinical benefit with the requested agent AND 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 4. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Length of Approval:</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>Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the program quantity limit OR 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication AND 2. There is support for therapy with a higher dose for the requested indication OR B. BOTH of the following: <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND

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	<p style="text-align: center;">2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit OR</p> <p>C. BOTH of the following:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication AND 2. There is support for therapy with a higher dose for the requested indication <p>Length of Approval: 12 months</p>