



Xphozah Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
01-01-2026

Date of Origin
02-15-2024

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Xphozah	tenapanor hcl tab	20 MG ; 30 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
Xphozah	tenapanor hcl tab	20 MG	60	Tablets	30	DAYS			
Xphozah	tenapanor hcl tab	30 MG	60	Tablets	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Xphozah	tenapanor hcl tab	20 MG ; 30 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2026 ; Topaz ; Whole Foods

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Xphozah	tenapanor hcl tab	20 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Xphozah	tenapanor hcl tab	30 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2026 ; Topaz ; Whole Foods

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Initial Evaluation</p> <p>PREREQUISITE AGENTS</p> <p>Prerequisite generic agent(s)</p> <p>calcium carbonate calcium acetate calcium with magnesium lanthanum carbonate sevelamer carbonate sevelamer HCl</p> <p>PREFERRED AGENT(S) Ferric citrate 1 gm (210 mg ferric iron)</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed OR B. BOTH of the following: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of chronic kidney disease (CKD) AND ALL of the following: <ol style="list-style-type: none"> 1. The patient is on dialysis AND

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	<ol style="list-style-type: none"> <li data-bbox="662 180 1398 237">2. The patient has a phosphorus level of at least 5.5 mg/dL AND <li data-bbox="662 260 964 289">3. ONE of the following: <ol style="list-style-type: none"> <li data-bbox="760 312 1076 342">1. BOTH of the following: <ol style="list-style-type: none"> <li data-bbox="857 365 1157 394">1. ONE of the following: <ol style="list-style-type: none"> <li data-bbox="948 396 1409 537">A. The prescriber has stated that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR <li data-bbox="948 539 1409 764">B. The prescriber has submitted documentation that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat an associated condition related to stage four advanced metastatic cancer AND <li data-bbox="857 766 1409 991">2. The use of the requested agent is consistent with best practices for the treatment of stage four advanced, metastatic cancer, or an associated condition; supported by peer-reviewed, evidence-based literature; and approved by the United States Food and Drug Administration OR <li data-bbox="760 993 1076 1022">2. BOTH of the following: <ol style="list-style-type: none"> <li data-bbox="857 1045 1157 1075">A. ONE of the following: <ol style="list-style-type: none"> <li data-bbox="948 1098 1409 1239">1. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR <li data-bbox="948 1262 1409 1402">2. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR <li data-bbox="948 1425 1409 1545">3. The patient has tried and had an inadequate response to at least ONE prerequisite agent [chart notes required] OR <li data-bbox="948 1568 1409 1688">4. The patient has an intolerance or hypersensitivity to ONE prerequisite agent [chart notes required] OR <li data-bbox="948 1711 1409 1831">5. The patient has an FDA labeled contraindication to ALL prerequisite agents [chart notes required] OR <li data-bbox="948 1854 1409 1932">6. ONE prerequisite agent was discontinued due to lack of efficacy or effectiveness,

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	<p>diminished effect, or an adverse event [chart notes required] OR</p> <p>7. ONE prerequisite agent is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR</p> <p>8. ONE prerequisite agent is NOT in the best interest of the patient based on medical necessity [chart notes required] OR</p> <p>9. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE prerequisite agent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] AND</p> <p>B. ONE of the following:</p> <ol style="list-style-type: none"> 1. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR 2. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR 3. The patient has tried and had an inadequate response to at least ONE preferred agent [chart notes required] OR 4. The patient is intolerant or has a hypersensitivity to ONE preferred agent [chart notes required] OR 5. The patient has an FDA labeled contraindication to ALL preferred agent(s) [chart notes required] OR

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	<p>6. A preferred agent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR</p> <p>7. A preferred agent is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR</p> <p>8. A preferred agent is NOT in the best interest of the patient based on medical necessity [chart notes required] OR</p> <p>9. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as a preferred agent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] AND</p> <p>4. ONE of the following:</p> <p>A. The patient will be using phosphate binder therapy in combination with the requested agent OR</p> <p>B. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to phosphate binder therapy OR</p> <p>B. The patient has another FDA labeled indication for the requested agent and route of administration AND</p> <p>2. If the patient has an FDA labeled indication, then ONE of the following:</p> <p>A. The patient's age is within FDA labeling for the requested indication for the requested agent OR</p> <p>B. There is support for using the requested agent for the patient's age for the requested indication AND</p> <p>2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND</p> <p>3. The patient does NOT have any FDA labeled contraindications to the requested agent</p>

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	<p>Length of Approval:</p> <p>BCBSOK: 36 months ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>The requested agent will also be approved when ONE of the following is met:</p> <ol 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 style="list-style-type: none"> A. The patient does NOT have any FDA labeled contraindications to the requested agent AND B. The requested indication is a rare disease AND C. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 2. ALL of the following: <ol style="list-style-type: none"> A. The member resides in Ohio AND B. The plan is Fully Insured or HIM Shop (SG) AND C. The patient does NOT have any FDA labeled contraindications to the requested agent AND D. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 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] <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 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:

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	<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 <p>B. BOTH of the following:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND 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>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>