



Pancreatic Enzymes Prior Authorization Program Summary

POLICY REVIEW CYCLE

Effective Date

01-01-2026

Date of Origin

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Creon ; Pancreaze ; Pertzye ; Zenpep	pancrelipase (lip-prot-amyl) dr cap	10000-32000 UNIT ; 10500-35500 UNIT ; 12000-38000 UNIT ; 15000-47000 UNIT ; 16000-57500 UNIT ; 16800-56800 UNIT ; 20000-63000 UNIT ; 21000-54700 UNIT ; 24000-76000 UNIT ; 24000-86250 UNIT ; 25000-79000 UNIT ; 2600-8800 UNIT ; 3000-10000 UNIT ; 3000-9500 UNIT ; 36000-114000 UNIT ; 37000-97300 UNIT ; 4000-14375 UNIT ; 40000-126000 UNIT ; 4200-14200 UNIT ; 5000-24000 UNIT ; 6000-19000 UNIT ; 60000-189600 UNIT ; 8000-28750 UNIT	M ; N ; O ; Y	N		
Viokace	pancrelipase (lip-prot-amyl) tab	10440-39150 UNIT ; 20880-78300 UNIT	M ; N ; O ; Y	N		

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Creon ; Pancreaze ; Pertzye ; Zenpep	pancrelipase (lip-prot-amyl) dr cap	10000-32000 UNIT ; 10500-35500 UNIT ; 12000-38000 UNIT ; 15000-47000 UNIT ; 16000-57500 UNIT ; 16800-56800 UNIT ; 20000-63000 UNIT ; 21000-54700 UNIT ; 24000-76000 UNIT ; 24000-86250 UNIT ; 25000-79000 UNIT ; 2600-8800 UNIT ; 3000-	IL HMO Performance Annual ; 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

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
		10000 UNIT ; 3000-9500 UNIT ; 36000-114000 UNIT ; 37000-97300 UNIT ; 4000-14375 UNIT ; 40000-126000 UNIT ; 4200-14200 UNIT ; 5000-24000 UNIT ; 6000-19000 UNIT ; 60000-189600 UNIT ; 8000-28750 UNIT	Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026
Viokace	pancrelipase (lip-prot-amyl) tab	10440-39150 UNIT ; 20880-78300 UNIT	IL HMO Performance Annual ; 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 ; TX HIM Annual 2025 ; TX HIM Annual 2026

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval		
	<p>Initial Evaluation</p> <p>Target Agent(s) will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> The requested agent is eligible for continuation of therapy AND the following: <table border="1" data-bbox="521 1171 1203 1262"> <thead> <tr> <th>Agents Eligible for Continuation of Therapy</th> </tr> </thead> <tbody> <tr> <td>All target agents are eligible for continuation of therapy</td> </tr> </tbody> </table> ALL of the following: <ol style="list-style-type: none"> 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 The patient has an FDA labeled indication or an indication supported in compendia for the requested agent AND <ol style="list-style-type: none"> If the requested agent is Pancreaze, Pertzye, or Viokace, then ONE of the following: <ol style="list-style-type: none"> The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes are required] OR The patient has tried and had an inadequate response to BOTH Creon and Zenpep [chart notes are required] OR BOTH Creon and Zenpep were discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] OR The patient has an intolerance or hypersensitivity to BOTH Creon and Zenpep that is not expected to occur with the requested agent [chart notes are required] OR The patient has an FDA labeled contraindication to BOTH Creon and Zenpep that is not expected to occur with the requested agent [chart notes are required] OR 	Agents Eligible for Continuation of Therapy	All target agents are eligible for continuation of therapy
Agents Eligible for Continuation of Therapy			
All target agents are eligible for continuation of therapy			

Module	Clinical Criteria for Approval
	<p>7. BOTH Creon and Zenpep are 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 are required] OR</p> <p>8. BOTH Creon and Zenpep are not in the best interest of the patient based on medical necessity [chart notes are 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 BOTH Creon and Zenpep and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes are required] AND</p> <p>C. If the patient has an FDA labeled indication, then ONE of the following:</p> <ol style="list-style-type: none"> 1. The patient’s age is within FDA labeling for the requested indication for the requested agent OR 2. There is information in support of using the requested agent for the patient’s age for the requested indication AND <p>D. If the request is for Viokace, the patient will take with a proton pump inhibitor (PPI) AND</p> <p>E. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., cystic fibrosis, gastroenterologist) or the prescriber has consulted with a specialist in the area of the patient’s diagnosis AND</p> <p>F. The patient does not have any FDA labeled contraindications to the requested agent AND</p> <p>G. ONE of the following:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed 10,000 units/kg/day OR 2. BOTH of the following: <ol style="list-style-type: none"> A. The requested quantity (dose) exceeds 10,000 units/kg/day AND B. Information has been provided in support of therapy with a higher dose for the requested indication <p>Length of approval:</p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>Compendia Allowed: AHFS, DrugDex 1, 2a, or 2b level of evidence, or NCCN 1, 2a, or 2b recommended use</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 MT Fully Insured or MT HIM member AND <ol style="list-style-type: none"> A. The patient is under the age of 18 years old AND B. The patient does NOT have any FDA labeled contraindications to the requested agent AND C. The patient has an indication that is supported in TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] 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] AND D. There is support for an age in the patient’s given age bracket in TWO articles from major peer-reviewed professional medical journals as generally safe and effective. The age brackets are: 1. infancy (birth up to, but not including, 2 years of age), 2. childhood (2 years of age through 11 years of age), 3. adolescence

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	<p>(12 years of age through 17 years of age). 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] OR</p> <p>2. ALL of the following:</p> <ul 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: <ul 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</p> <p>ALL other plans: 12 months</p> <p>Renewal Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ul 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., cystic fibrosis, gastroenterologist) 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 5. ONE of the following: <ul style="list-style-type: none"> A. The requested quantity (dose) does NOT exceed 10,000 units/kg/day OR B. BOTH of the following: <ul style="list-style-type: none"> 1. The requested quantity (dose) exceeds 10,000 units/kg/day AND 2. Information has been provided in support of therapy with a higher dose for the requested indication <p>Length of Approval:</p> <p>BCBSOK: 36 months</p>

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	ALL other plans: 12 months