

# PRIOR AUTHORIZATION CRITERIA

<b>DRUG CLASS</b>	<b>PANCREATIC ENZYMES</b>
<b>BRAND NAME* (generic)</b>	<b>CREON (pancrelipase)</b>
	<b>PANCREAZE (pancrelipase)</b>
	<b>PERTZYE (pancrelipase)</b>
	<b>VIOKACE (pancrelipase)</b>
	<b>ZENPEP (pancrelipase)</b>
<b>Status: CVS Caremark® Criteria</b>	
<b>Type: Initial Prior Authorization</b>	
<b>Ref # 3134-A</b>	

\*Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.

## FDA-APPROVED INDICATIONS

### **Creon**

Creon (pancrelipase) is indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis, chronic pancreatitis, pancreatectomy, or other conditions.

### **Pancreaze, Pertzye, Zenpep**

Pancreaze, Pertzye, and Zenpep (pancrelipase) are indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions.

### **Viokace**

Viokace (pancrelipase) tablets, in combination with a proton pump inhibitor, is indicated in adults for the treatment of exocrine pancreatic insufficiency due to chronic pancreatitis or pancreatectomy.

## COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis, chronic pancreatitis, pancreatectomy, or other conditions

### **AND**

- If the request is for Viokace, the patient will take Viokace in combination with a proton pump inhibitor (PPI)

Duration of Approval (DOA):

Pancrelipase PA Policy 3134-A UDR 10-2023

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

©2023 CVS Health and/or its affiliates. All rights reserved. 106-58428A 021423

- 3134-A: DOA: 12 months

## **RATIONALE**

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Creon (pancrelipase) is indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis, chronic pancreatitis, pancreatectomy, or other conditions.<sup>1</sup> Pancreaze, Pertzye, and Zenpep (pancrelipase) are indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions.<sup>2,3,5</sup> Viokace (pancrelipase) tablets, in combination with a proton pump inhibitor, is indicated in adults for the treatment of exocrine pancreatic insufficiency due to chronic pancreatitis or pancreatectomy.<sup>4</sup> Pancrelipase is not effective in the treatment of functional digestive disorders unrelated to pancreatic insufficiency.<sup>6</sup>

## **REFERENCES**

1. Creon [package insert]. North Chicago, IL: AbbVie Inc.; June 2022.
2. Pancreaze [package insert]. Campbell, CA: Vivus LLC.; January 2022.
3. Pertzye [package insert]. Bethlehem, PA: Digestive Care, Inc.; September 2022.
4. Viokace [package insert]. Bridgewater, NJ: Nestlé HealthCare Nutrition, Inc.; March 2020.
5. Zenpep [package insert]. Bridgewater, NJ: Nestlé HealthCare Nutrition, Inc.; March 2020.
6. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. <https://online.lexi.com>. Accessed August 31, 2023.
7. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 08/31/2023).

Written by: UM Development (KC)  
Date Written: 07/2019  
Revised: (KC) 09/2019 (no clinical changes), (MAC) 09/2020 (no clinical changes), (JK) 09/2021 (no clinical changes), (VLS) 09/2022 (no clinical changes); (SS) 09/2023 (no clinical changes)  
Reviewed: Medical Affairs (CHART) 08/08/19, 09/26/19, 09/24/20, 09/30/21, (CHART) 09/22/2022, 09/28/2023  
External Review: 08/2019, 12/2019, 12/2020, 12/2021, 12/2022, 12/2023

Pancrelipase PA Policy 3134-A UDR 10-2023

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

©2023 CVS Health and/or its affiliates. All rights reserved. 106-58428A 021423