

# PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	PANCREATIC ENZYMES
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BRAND NAME* (generic)	
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	CREON (pancrelipase)
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	PANCREAZE (pancrelipase)
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	PERTZYE (pancrelipase)
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	VIOKACE (pancrelipase)
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	ZENPEP (pancrelipase)
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**Status: CVS Caremark Criteria**

**Type: Initial Prior Authorization**

**Ref # 3134-A**

*\* 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 with a proton pump inhibitor (PPI)

## **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.; March 2020.
2. Pancreaze [package insert]. Campbell, CA: Vivus, Inc.; October 2018.
3. Pertzye [package insert]. Bethlehem, PA: Digestive Care, Inc.; March 2020.
4. Viokace [package insert]. Madison, NJ: Allergan USA, Inc.; March 2020.
5. Zenpep [package insert]. Madison, NJ: Allergan USA, Inc.; March 2020.
6. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed September 2020.
7. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed September 2020.

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## **CRITERIA FOR APPROVAL**

1	Is the requested drug being prescribed for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis, chronic pancreatitis, pancreatectomy, or other conditions? [If no, then no further questions.]	Yes	No
2	Is this request for Viokace (pancrelipase)? [If no, then no further questions.]	Yes	No
3	Will the patient take Viokace (pancrelipase) with a proton pump inhibitor (PPI)?	Yes	No

### **Mapping Instructions**

#### **DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**

	<b>Yes</b>	<b>No</b>	
1.	Go to 2	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you meet the following condition: - You have pancreatic insufficiency caused by another condition Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
2.	Go to 3	Approve, 12 months	
3.	Approve, 12 months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you will be taking a proton pump inhibitor (PPI) with Viokace. Your request has been denied based on the information we have. [Short Description: Not taking Viokace with a PPI]