

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	PANCREATIC ENZYMES
BRAND NAME* (generic)	CREON (pancrelipase) PANCREAZE (pancrelipase) PERTZYE (pancrelipase) VIOKACE (pancrelipase) ZENPEP (pancrelipase)
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 Viokace in combination with a proton pump inhibitor (PPI)

Duration of Approval (DOA):

- 3134-A: DOA: 12 months

Pancrelipase PA 3134-A UDR 10-2023.docx

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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.¹ Pancreaze, Pertzye, and Zenpep (pancrelipase) are indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions.^{2,3,5} 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.⁴ Pancrelipase is not effective in the treatment of functional digestive disorders unrelated to pancreatic insufficiency.⁶

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)
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