

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3030-13
Program	Step Therapy
Medication	Pancreaze [®] , Pertzze [®] , Viokace [®]
P&T Approval Date	7/2014, 7/2015, 7/2016, 7/2017, 7/2018, 7/2019, 7/2020, 7/2021, 7/2022, 7/2023, 7/2024
Effective Date	10/1/2024

1. Background:

The pancrelipase products of Creon, Pancreaze, Pertzze and Zenpep are indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions. Viokace is indicated in combination with a proton pump inhibitor for the treatment of exocrine pancreatic insufficiency due to chronic pancreatitis or pancreatectomy in adults.

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try Creon and Zenpep before providing coverage for Pancreaze, Pertzze or Viokace.

Members, who have received at least a 90 day supply of Pancreaze, Pertzze or Viokace in the past 120 days as documented in claims history, will be allowed continued coverage of their current therapy.

2. Coverage Criteria^a:

<p>A. Pancreaze, Pertzze or Viokace will be approved based on the following criterion:</p> <ol style="list-style-type: none"> 1. History of failure, contraindication or intolerance to both of the following medications: <ol style="list-style-type: none"> a. Creon b. Zenpep <p style="text-align: center;">Authorization will be issued for 12 months.</p> <p>^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.</p>

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. Creon [package insert]. North Chicago IL: AbbVie Inc.; February 2024.
2. Pancreaze [package insert]. Campbell, CA: Vivus, Inc; February 2024.
3. Pertzye [package insert]. Bethlehem, PA: Digestive Care, Inc.; February 2024.
4. Viokace [package insert]. Bridgewater, NJ: Aimmune Therapeutics, Inc; February 2024.
5. Zenpep [package insert]. Bridgewater, NJ: Aimmune Therapeutics, Inc; February 2024.

Program	Step Therapy – Pancreatic Enzyme Products (PEPs)
Change Control	
Date	Change
7/2014	New program.
7/2015	Annual Review. Updated authorization timeframe.
10/2015	Administrative update. Added Maryland Continuation of Care.
7/2016	Decreased authorization period to 12 months. Updated References. Added Indiana and West Virginia coverage information.
11/2016	Administrative change. Added California coverage information.
7/2017	Annual review. Updated references.
7/2018	Annual review. Removed Ultresa since longer available on the market. Updated references.
7/2019	Annual review. Added an authorization look back for current users and updated references.
7/2020	Annual review. Updated references.
7/2021	Annual review. Updated background section and references.
7/2022	Annual review. Updated references.
7/2023	Annual review. Updated references.
7/2024	Annual review. Updated references.