



**UnitedHealthcare Individual & Family ACA Marketplace Plans
Clinical Pharmacy Program Guidelines for Pancreatic Enzymes**

Program	Step Therapy – Pancreatic Enzymes
Medication	Pertzye (pancrelipase)
Issue Date	9/2020
Pharmacy and Therapeutics Approval Date	7/2023
Effective Date	9/2023

1. Background:

Pertzye (pancrelipase) is a pancreatic enzyme indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions.

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try two alternative pancreatic enzymes – Creon (pancrelipase) and Zenpep (pancrelipase) – prior to receiving coverage for Pertzye.

2. Coverage Criteria ^a:

<p>A. Pertzye 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. Creonb. Zenpep <p 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.
- Supply limits may be in place

4. References:

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1. Creon [package insert]. North Chicago IL: AbbVie Inc.; June 2022.
2. Pertzye [package insert]. Bethlehem, PA: Digestive Care, Inc.; September 2022.
3. Zenpep [package insert]. Bridgewater, NJ: Nestle Healthcare Nutrition, Inc; March 2020.

Program	Step Therapy – Pancreatic Enzymes
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.
10/2020	Revised background, added specific step therapy exemption state mandates, and removed Pancreaze and Viokace as target drugs.
12/2020	Removed unnecessary state mandate specific language pertaining to MD, OK, VA and left generalized state mandate language for PA team to reference state mandates grid as appropriate for UnitedHealthcare Value & Balance Exchange for 1/2021 implementation.
7/2021	Annual review. Updated Additional Clinical Rules section and references.
9/2021	Review for 2022 implementation. Removed detailed definition of step therapy from background.
7/2022	Annual review, no changes to clinical criteria.
7/2023	Annual review. Updated references.