Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Pancreatic Enzymes Step Therapy

Effective: January 1, 2026

Guideline Type	☐ Prior Authorization ☐ Non-Formulary ☒ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Pancreaze (pancrelipase) and **Pertzye (pancrelipase)** are indicated for the treatment of exocrine pancreatic insufficiency in adults and pediatric patients.

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

Clinical Guideline Coverage Criteria

Note: Prescriptions that meet the initial step therapy requirements will adjudicate **automatically** at the point of service. If the patient does not meet the initial step therapy criteria, the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Refer to the Coverage Criteria below and submit PA requests to the plan for patients who do not meet the step therapy criteria at the point of service.

Please refer to the table below for medications subject to this policy:

Drug	CoreMA, Direct, Premium, Select, Value
Step-1	
Creon	Covered
Zenpep	
Step-2	
Pancreaze	Requires prior use of both drugs on Step-1
Pertzye	
Viokace	

Drug	Core NH, Core ME, Core RI
Step-1	
Creon	Covered
Zenpep	
Step-2	
Pancreaze	Requires prior use of both drugs on Step-1
Pertzye	Non-formulary
Viokace	

Automated Step Therapy Coverage Criteria

The following stepped approach applies to coverage of the Step-2 medications by the plan:

Step 1: Medications on Step-1 are covered without prior authorization.

Step 2: The plan may cover Step-2 medications if the following criteria are met:

The patient has had a trial of both Step-1 medications, or the requested Step-2 medication within the previous 999 days as evidenced by a previous paid claim under the prescription benefit administered by the plan.

Coverage Criteria for Patients not meeting the Automated Step Therapy Coverage Criteria at the Point of Sale

The following stepped approach applies to Step-2 pancreatic enzyme medications covered by the plan:

Step 2: The plan may cover medications on Step-2 if the following criteria are met:

1. The patient has had a trial of both Step-1 medications as evidenced by physician's documented use, excluding the use of samples

OR

2. The patient has a physician documented contraindication or intolerance to ALL Step-1 medications.

Limitations

1. Step therapy point of service coding does not apply to any non-formulary medications.
2. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.
3. Previous use of samples or vouchers/coupons for brand name medications will not be considered for authorization.

Codes

None

References

1. Pancreaze (pancrelipase) [prescribing information]. Campbell, CA: Vivus, Inc; June 2025.
2. Pertzye (pancrelipase) [prescribing information]. Bethlehem, PA: Digestive Care, Inc. March 2024.
3. Viokace (pancrelipase) [prescribing information]. Irvine, CA: Allergan USA, Inc. August 2025.

Approval And Revision History

September 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- July 11, 2023: No changes
- October 10, 2023: Effective November 1, 2023, converted the three-step program to two-step by combining Creon (Step 1) and Zenpep (Step 2) as Step 1, and Pancreaze, Pertzye and Viokace as Step 2. Administrative update to step therapy table.
- October 8, 2024: Effective January 1, 2025, added Direct, Core ME and CoreRI coverage to step therapy program chart.
- October 14, 2025: Effective January 1, 2026, administrative update to add Core MA and Select formularies to step therapy program chart.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.