Effective Date **4/1/2024**
Next Review Date… **4/1/2025**
Coverage Policy Number **IP0002**

Pancrelipase

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for the following pancrelipase products:

- **Creon**® (pancrelipase delayed-release capsules)
- **Pertzye**® (pancrelipase delayed-release capsules)
- **Zenpep**® (pancrelipase delayed-release capsules)

Additional criteria that support the review for medical necessity exceptions of non-covered products are located in the Non-Covered Product Table by the respective plan type and drug list where applicable.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Pancrelipase products (Creon, Pertzye, Zenpep) are considered medically necessary when the following are met:

Exocrine Pancreatic Insufficiency. Individual meets the **BOTH** of the following criteria:

A. Treatment of exocrine pancreatic insufficiency due to cystic fibrosis, chronic pancreatitis, pancreatectomy, or other conditions
B. Non-Covered Product Criteria is met, refer to below table(s)

Employer Group Non-Covered Products and Criteria:

Non-Covered Product	Criteria
Creon (pancrelipase delayed-release capsules)	Documentation of failure, contraindication, or intolerance to Pancreaze (pancrelipase)
Pertzye (pancrelipase delayed-release capsules)	Documentation of failure, contraindication, or intolerance to Pancreaze (pancrelipase)
Zenpep (pancrelipase delayed-release capsules)	Documentation of failure, contraindication, or intolerance to Pancreaze (pancrelipase)

Individual and Family Plan Non-Covered Products and Criteria:

Non-Covered Product	Criteria
Zenpep (pancrelipase delayed-release capsules)	Documentation of failure, contraindication, or intolerance to Pancreaze (pancrelipase)

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of pancrelipase products (Creon, Pertzye, Zenpep) is considered medically necessary for Exocrine Pancreatic Insufficiency when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Background

OVERVIEW
The pancreatic enzyme products are indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions.[1-4] Creon is also specifically indicated for the treatment of exocrine pancreatic insufficiency due to chronic pancreatitis and pancreatectomy.[1]

All of these pancreatic enzyme products consist of pancrelipase, an extract derived from porcine pancreatic glands.[1-4] Multiple enzyme classes are contained within the pancreatic enzyme products including porcine-derived lipases, proteases, and amylases.[5] These products are dosed by lipase units and lipase is the active ingredient that is generally evaluated in clinical trials. There are no dosage recommendations for switching patients between products from different manufacturers.[6] However, a review article notes a practical method would be to use a 1:1 lipase unit conversion for initial dosing and then titrating to efficacy.[7,8]

References

1. Creon® delayed release capsules [prescribing information]. North Chicago, IL: AbbVie; March 2020.
2. Pancreaze® delayed release capsules [prescribing information]. Campbell, CA: Vivus; April 2021.
3. Pertzye® capsules [prescribing information]. Bethlehem, PA: Digestive Care; March 2020.
4. Zenpep® delayed release capsules [prescribing information]. Madison, NJ: Allergan; March 2020.
5. Ferrone M, Raimondo M, Scolapio JS. Pancreatic enzyme pharmacotherapy. Pharmacotherapy. 2007;27:910-920.
6. Fieker A, Philpott J and Armand M. Enzyme replacement therapy for pancreatic insufficiency: present and future. Clin Exp Gastroenterol. 2011;4:55-73.
7. Giuliano CA, Dehoome-Smith M, Kale Pradha PB. Pancreatic enzyme products: digesting the changes. Ann Pharmacother. 2011;45:658-666.
8. Kalnins D and Wilschanski M. Maintenance of nutritional status in patients with cystic fibrosis: new and emerging therapies. Drug Des Devel Ther. 2012;6:151-161.