

Drug and Biologic Coverage Policy



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 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 pancrelipase products.

Coverage Policy Statement

Pancrelipase products are medically necessary when the following are met:

1. Criteria associated with FDA Indications
2. Criteria associated with Other Uses with Supportive Evidence
3. Specific Additional Criteria [when part of Cigna managed drug list or plan requirements]
4. Preferred Product Requirement Criteria [when part of Cigna managed drug list or plan requirements]

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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.

Approval duration is 12 months unless otherwise stated.

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

Documentation: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents. Documentation may include, but is not limited to, chart notes, prescription claims records, and/or prescription receipts

Refer to each criteria section below.

FDA Indication Criteria

Treatment of exocrine pancreatic insufficiency due to cystic fibrosis, chronic pancreatitis, pancreatectomy, or other conditions

Other Uses with Supportive Evidence Criteria

NONE

Specific Additional Criteria

NONE

Preferred Product Requirement Criteria

Coverage varies across plans. Refer to the customer's benefit plan document for coverage details. Where coverage requires the use of preferred products, the following criteria apply:

Approve for an individual when there is documentation of ONE of the following:

- The individual has had inadequate efficacy OR contraindication according to FDA label OR significant intolerance to ALL of covered alternatives according to the table below **OR**
- The individual is not a candidate for ALL covered alternatives according to the table below due to being subject to a warning per the prescribing information (labeling), having a disease characteristic, individual clinical factor[s], or other attributes/conditions or is unable to administer and requires this dosage formulation

Employer Group Non-Covered Products and Preferred Covered Alternatives by Drug List:

Non-Covered Product	Standard / Performance	Value / Advantage	Cigna Total Savings	Legacy
Creon® (Pancrelipase) Pertyze® (Pancrelipase)	• Pancreaze® (Pancrelipase)			

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Non-Covered Product	Standard / Performance	Value / Advantage	Cigna Total Savings	Legacy
Zenpep® (Pancrelipase)				

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven. Criteria will be updated as new published data are available.

Background

Pancreatic enzyme products were historically exempted from the Food, Drug, and Cosmetic Act of 1938 and therefore did not require FDA approval.¹ This resulted in a variety of pancreatic enzyme products for healthcare providers to choose from; products were available in several formulations including microcapsules, enteric-coated capsules, and regular-release capsules/tablets. Differences in product design were formulated to allow for varying release of pancreatic enzymes to facilitate optimal fat absorption. Although these products were generally considered effective, patients switching between unapproved pancreatic enzyme products of similar enzyme units experienced treatment failures. This finding prompted the FDA to review unapproved products; the FDA reported large variability of response between the unapproved products. In April of 2004, the FDA mandated that all manufacturers of pancreatic enzyme products must file New Drug Applications (NDAs) and receive formal drug approval by April 2010.²

There are five FDA-approved pancreatic enzyme products: Creon, Pancreaze, Pertyze, Viokace, and Zenpep.³⁻⁸ The FDA will continue to review NDAs that have been submitted by manufacturers of unapproved products, and will approve additional products, provided they meet the required safety, efficacy, and quality standards.^{3,9}

References

1. Giuliano CA, Dehoome-Smith M, Kale Pradha PB. Pancreatic enzyme products: digesting the changes. *Ann Pharmacother*. 2011;45:658-666.
2. 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.
3. U.S Department of Health and Human Services Food and Drug Administration. Questions and answers for healthcare professionals and the public: Use an approved pancreatic enzymes product (PEP). Published April 12, 2010; updated May 17, 2012. Available at: <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm204745.htm>. Accessed on May 26, 2020.
4. Creon® delayed release capsules [prescribing information]. North Chicago, IL: Abbvie; March 2020.
5. Pancreaze™ delayed release capsules [prescribing information]. Campbell, CA: Vivus, Inc; June 2018.
6. Pertyze™ capsules [prescribing information]. Bethlehem, PA: Digestive Care, Inc; July 2017.
7. Viokace® tablets [prescribing information]. Madison, NJ: Allergan; March 2020.
8. Zenpep® delayed release capsules [prescribing information]. Madison, NJ: Allergan; March 2020.
9. Food and Drug Administration. Exocrine pancreatic insufficiency drug products; extension to obtain marketing approval. *Federal Register*. 2007;72(207):60860. Available at: <http://edocket.access.gpo.gov/2007/pdf/E7-21080.pdf>. Accessed on May 26, 2020.

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