MEDICAL MUTUAL®

Drug Policy

Policy:	**Pancreatic Enzymes Preferred Step Therapy**	**Annual Review Date:** **03/17/2022**
Impacted Drugs:	**Pertzye (pancrelipase delayed release)**	**Last Revised Date:** **03/17/2022**

OVERVIEW

Pancreatic enzymes are indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis (CF) or other conditions. Creon is also specifically indicated for the treatment of exocrine pancreatic insufficiency due to chronic pancreatitis and pancreatectomy. Pancreatic enzymes (lipase, protease, and amylase) catalyze the hydrolysis of fats to monoglycerol, glycerol, and fatty acids, protein into peptides and amino acids, and starch into dextrins and short chain sugars. All of these products consist of pancrelipase, an extract from porcine pancreatic glands. The pancreatic enzymes included in this step therapy program are enteric-coated products. There is one non-enteric coated product, Viokace, which is not included. The enteric coating allows for uniform mixing in the stomach without release of contents until timely delivery into the duodenum.

Table 1. FDA-approved† PEP Contents.

Trade Name	Lipase Content	Protease Content	Amylase Content
Creon	3,000	9,500	15,000
	6,000	19,000	30,000
	12,000	38,000	60,000
	24,000	76,000	120,000
	36,000	114,000	180,000
Pancreaze	4,200	10,000	17,500
	10,500	25,000	43,750
	16,800	40,000	70,000
	21,000	37,000	61,000
Pertzye	8,000	28,750	30,250
	16,000	57,500	60,500
Viokace*	10,440	39,150	39,150
	20,880	78,300	78,300
Zenpep	3,000	10,000	16,000
	5,000	17,000	27,000
	10,000	34,000	55,000
	15,000	51,000	82,000
	20,000	68,000	109,000
	25,000	85,000	136,000
	40,000	136,000	218,000

FDA – Food and Drug Administration; PEP – Pancreatic enzyme product; †FDA-approved as of May 8, 2013. *Viokace is not included as part of this preferred step therapy program; it is listed for information purposes.

POLICY STATEMENT

A preferred step therapy program has been developed to encourage the use of a preferred product prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a non-preferred agent at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a history of two Step 1 Products within the 130-day look-back period is excluded from Step Therapy.

Preferred Medications

- Creon (pancrelipase delayed release)
- Pancreaze (pancrelipase delayed release)
- Zenpep (pancrelipase delayed release)

Non-Preferred Medications

- Pertzye (pancrelipase delayed release)

PREFERRED STEP THERAPY CRITERIA

1. If the patient has tried two preferred medications, then authorization for a non-preferred medication may be given.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

Step Therapy Exception Criteria
In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period

AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR

2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Pertzye® capsules [prescribing information]. Bethlehem, PA: Digestive Care, Inc;July 2017.
2. Ultresa® delayed-release capsules [prescribing information]. Bridgewater, NJ: Aptalis Pharma US, Inc; September 2014.
3. Zenpep® delayed release capsules [prescribing information]. Bridgewater, NJ: Aptalis Pharma US, Inc; March 2017.
4. Pancreaze® delayed release capsules [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; August 2016.
5. Creon® delayed release capsules [prescribing information]. North Chicago, IL: AbbVie; March 2015.
6. Pancrelipase™ capsules [prescribing information]. Big Flats, NY: X-Gen Pharmaceuticals Inc.; July 2013.