

## PREFERRED STEP THERAPY POLICY

- POLICY:** Pancreatic Enzymes (Enteric-Coated) Preferred Step Therapy Policy
- Creon® (pancrelipase delayed-release capsules – AbbVie)
  - Pancreaze® (pancrelipase delayed-release capsules – Janssen)
  - Pertzye® (pancrelipase delayed-release capsules – Digestive Care)
  - Zenpep® (pancrelipase delayed-release capsules – Actavis)

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### OVERVIEW

The **pancreatic enzyme products** are indicated for the treatment of **exocrine pancreatic insufficiency due to cystic fibrosis (CF) or other conditions**.<sup>1-4</sup> **Creon** is also specifically indicated for the treatment of **exocrine pancreatic insufficiency due to chronic pancreatitis and pancreatectomy**.<sup>1</sup>

All of these pancreatic enzyme products consist of pancrelipase, an extract derived from porcine pancreatic glands.<sup>1-4</sup> Multiple enzyme classes are contained within the pancreatic enzyme products including porcine-derived lipases, proteases, and amylases.<sup>5</sup> These products are dosed by lipase units and lipase is the active ingredient that is generally evaluated in clinical trials. The pancreatic enzymes 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 in the duodenum and proximal small intestines, thereby acting like digestive enzymes physiologically secreted by the pancreas.

All of the pancreatic enzyme products are indicated for use in children and adults. Creon, Pancreaze, Pertzye, and Zenpep are indicated in infants up to 12 months of age, children, and adults.<sup>1-4,6</sup> The recommended dose is 2,000 lipase units to 4,000 lipase units per 120 mL of formula or breast milk for infants up to 12 months of age.<sup>1-4</sup> All of the delayed-release pancreatic enzyme products can be opened and sprinkled over acidic food (e.g., applesauce).

There are no dosage recommendations for switching patients between products from different manufacturers.<sup>6</sup> 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.<sup>7,8</sup>

**Table 1. Pancreatic Enzyme Content.**<sup>1-4</sup>

Brand 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	2,600	6,200	10,850
	4,200	14,200	24,600
	10,500	35,500	61,500
	16,800	56,800	98,400
	21,000	54,700	83,900

**Table 1 (continued). Pancreatic Enzyme Content.**<sup>1-4</sup>

Brand Name	Lipase Content	Protease Content	Amylase Content
Pertzye	4,000	14,375	15,125
	8,000	28,750	30,250
	16,000	57,500	60,500
	24,000	86,250	90,750
Zenpep	3,000	10,000	14,000
	5,000	17,000	24,000
	10,000	32,000	42,000
	15,000	47,000	63,000
	20,000	63,000	84,000
	40,000	126,000	168,000

**POLICY STATEMENT**

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Preferred Step Therapy rule is not met for a Step 2 Product 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.

**Step 1:** Creon, Pancreaze, Zenpep

**Step 2:** Pertzye

**CRITERIA**

1. If the patient has tried two Step 1 Products, approve a Step 2 Product.
2. No other exceptions are recommended.

**REFERENCES**

1. Creon<sup>®</sup> delayed release capsules [prescribing information]. North Chicago, IL: AbbVie; March 2020.
2. Pancreaze<sup>®</sup> delayed release capsules [prescribing information]. Campbell, CA: Vivus, Inc; June 2018.
3. Pertzye<sup>®</sup> capsules [prescribing information]. Bethlehem, PA: Digestive Care, Inc; March 2020.
4. Zenpep<sup>®</sup> 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.