

Commercial/Healthcare Exchange Step Criteria

Effective: January 1, 2020

Step Therapy Name: Pancreatic Enzymes

Step 1 Agent(s): Creon, Zenpep

Step 2 Agent(s): Pertzye, Pancreaze, Viokace

Medication/Class Description: 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. The enteric coating allows for uniform mixing in the stomach without release of contents until timely delivery into the duodenum.

Required Medical Information:

1. Previous therapies tried/failed

Age Restrictions:

Viokace: 18 years of age and older

Prescriber Restrictions: N/A

Coverage Duration: 12 months

Exceptions for Stepped Medications

1. Patient has had a trial and failure of Creon AND Zenpep, defined as:
 - a. Failure to improve symptoms of pancreatic insufficiency, Cystic fibrosis or other conditions. **OR**
2. Patient has an intolerance or contraindication to Creon AND Zenpep, defined as (but not limited to):
 - a. Allergic reaction;
 - b. Adverse drug reactions.

References:

1. Product Information: PANCREAZE(R) oral delayed-release capsules, pancrelipase oral delayed-release capsules. Janssen Pharmaceuticals Inc. (per FDA), Titusville, NJ, 2014.
2. Product Information: PERTZYE(TM) oral delayed-release capsules, pancrelipase oral delayed-release capsules. Digestive Care, Inc. (per Manufacturer), Bethlehem, PA, 2012.
3. Product Information: VIOKACE(TM) oral tablets, pancrelipase oral tablets. Aptalis Pharma US, Inc (Per FDA), Birmingham, AL, 2012.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	10/18/2019

Last Reviewed: 10/18/2019