

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Pancreatic Enzyme Agents PDL Edit
<b>First Implementation Date:</b>	June 23, 2011
<b>Proposed Date:</b>	March 18, 2021
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

**Why Issue Selected:** The exocrine functions of the pancreas include the secretion of an isotonic fluid that contains, among other things, pancreatic enzymes necessary for digestion. This fluid neutralizes gastric acid in the duodenum and achieves an appropriate pH for maintaining the activity of the enzymes. When this pancreatic function is lost, supplementation of the pancreatic enzymes is needed. Pancreatic enzymes are available in a variety of formulations and strengths. All formulations are measured by their content of amylase, lipase, and protease. In order to avoid gastric inactivation, enteric coatings and buffering may be used to deliver enzymes to the intestine. Pancreatic enzyme replacement therapy is indicated in patients with deficient exocrine pancreatic secretions, such as in cystic fibrosis (CF), chronic pancreatitis, post-pancreatectomy, ductal obstructions caused by cancer of the pancreas or common bile duct and pancreatic insufficiency, and for steatorrhea of malabsorption syndrome and postgastrectomy.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	<ul style="list-style-type: none"> <li>Creon®</li> <li>Zenpep®</li> </ul>	<ul style="list-style-type: none"> <li>Pancreaze®</li> <li>Pertzye®</li> <li>Viokace®</li> </ul>

**Type of Criteria:**  Increased risk of ADE  Preferred Drug List  
 Appropriate Indications  Clinical Edit

**Data Sources:**  Only Administrative Databases  Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Pancreatic Enzymes Agents
- Age range: All appropriate MO HealthNet participants

## Approval Criteria

- Documented compliance on current therapy regimen **OR**
- Failure to achieve desired therapeutic outcomes with trial on 2 preferred agents
  - Documented trial period of preferred agents
  - Documented ADE/ADR to preferred agents

## Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met

## Required Documentation

Laboratory Results:   
MedWatch Form:

Progress Notes:   
Other:

## Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)  
Rule Type: PDL

## Default Approval Period

1 year

## References

1. Evidence-Based Medicine and Fiscal Analysis: "Pancreatic Enzymes – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; March 2021.
2. Evidence-Based Medicine Analysis: "Pancreatic Enzyme Products", UMKC-DIC; February 2021.
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2021.
4. USPDI, Micromedex; 2021.
5. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.