SmartPA Criteria Proposal

Drug/Drug Class:	Pancreatic Enzyme Agents PDL Edit
First Implementation Date:	June 23, 2011
Revised Date:	January 12, 2023
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐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
• Creon®	• Pertzye®
• Zenpep®	• Viokace®

Type of Criteria:
☐ **Increased risk of ADE**
☐ **Appropriate Indications**
☒ **Preferred Drug List**
☐ **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:	☐	Progress Notes:	☐
MedWatch Form:	☐	Other:	☐

Disposition of Edit

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

Default Approval Period

1 year

References

- Evidence-Based Medicine and Fiscal Analysis: “Pancreatic Enzymes – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; January 2022.
- Evidence-Based Medicine Analysis: “Pancreatic Enzyme Products”, UMKC-DIC; October 2021.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.