

## Literature Scan: Pancreatic Enzymes

**Date of Review:** September 2018

**Date of Last Review:** September 2017

**End Date of Literature Search:** 07/03/2018

### **Current Status of PDL Class:**

See **Appendix 1**.

### **Purpose for Review:**

The purpose of this review is to evaluate any new evidence on the use of pancreatic enzymes since the previous literature scan done in 2017.

### **Research Questions:**

1. What is the evidence for comparative efficacy of different pancreatic enzyme preparations for important outcomes (i.e., coefficient of fat absorption)?
2. Is there evidence of differences in harms for the different pancreatic enzyme preparations?
3. Is there evidence of more benefit or harm in different subpopulations who use pancreatic enzymes?

### **Conclusions:**

- There was no new comparative evidence published in the last year on pancreatic enzyme replacement therapy (PERT) that met inclusion criteria for the literature scan as described in current methods. A list of PERT and corresponding indications are listed in **Appendix 3**.

### **Recommendations:**

- Recommend no changes to the preferred drug list (PDL) based on clinical efficacy information.
- After evaluation of comparative costs in executive session, make Zenpep® preferred on the PDL.

### **Summary of Prior Reviews and Current Policy**

- A literature scan was performed in September 2017 that found no evidence of efficacy or safety differences between the pancreatic enzyme preparations. Overall evidence is of low or insufficient quality and highly dependent on subjective patient records of food diaries. There were no changes to the PDL after executive session, with Creon and Pancrelipase MT 16 being the only preferred products. There are no prior authorization (PA) criteria for this class.

---

**Methods:**

A Medline literature search for new systematic reviews and randomized controlled trials (RCTs) assessing clinically relevant outcomes to active controls, or placebo if needed, was conducted. The Medline search strategy used for this review is available in **Appendix 2**, which includes dates, search terms and limits used. The OHSU Drug Effectiveness Review Project, Agency for Healthcare Research and Quality (AHRQ), the Cochrane Collaboration, National Institute for Health and Clinical Excellence (NICE), Department of Veterans Affairs, Institute for Clinical and Economic Review (ICER), and the Canadian Agency for Drugs and Technologies in Health (CADTH) resources were manually searched for high quality and relevant systematic reviews. When necessary, systematic reviews are critically appraised for quality using the AMSTAR tool and clinical practice guidelines using the AGREE tool. The FDA website was searched for new drug approvals, indications, and pertinent safety alerts. Finally, the AHRQ National Guideline Clearinghouse (NGC) was searched for updated evidence-based clinical practice guidelines.

The primary focus of the evidence is on high quality systematic reviews and evidence-based guidelines. Randomized controlled trials will be emphasized if evidence is lacking or insufficient from those preferred sources.

**New Systematic Reviews:**

No new systematic reviews identified.

**New Guidelines:**

No new guidelines identified.

**New Formulations or Indications:**

No new formulations or indications identified.

**New FDA Safety Alerts:**

No safety alerts identified.

**Randomized Controlled Trials:**

No new randomized controlled trials were identified.

**References:**

1. Creon Prescribing Information. AbbVie Inc. North Chicago, IL; 2015.
2. Pancreaze® Prescribing Information. Janssen Pharmaceuticals, Inc. Titusville, NJ; 2010.
3. Pancrealipase MT® Prescribing Information. McNeil Consumer & Specialty Pharmaceuticals. Ft. Washington, PA; 2005.
4. Pertyze Prescribing Information. Digestive Care, Inc. Bethlehem, PA; 2017.
5. Ultrace® Prescribing Information. Axcan Scandipharm INC. Birmingham, AL; 2005.
6. Ultresa Prescribing Information. Aptalis Pharma US, Birmingham, AL; 2012.
7. Viokase Prescribing Information. Aptalis Pharma US, Inc. Birmingham, AL; 2012.
8. Zenpep Prescribing Information. Eurand Pharmaceuticals, Inc. Yardley, PA; 2009.

---

**Appendix 1: Current Preferred Drug List**

<u>Generic</u>	<u>Brand</u>	<u>FormDesc</u>	<u>PDL</u>
lipase/protease/amylase	CREON	CAPSULE DR	Y
lipase/protease/amylase	PANCRELIPASE MT 16	CAPSULE DR	Y
lipase/protease/amylase	PANCREAZE	CAPSULE DR	N
lipase/protease/amylase	PANCRELIPASE 10000	CAPSULE DR	N
lipase/protease/amylase	PERTZYE	CAPSULE DR	N
lipase/protease/amylase	ULTRASE	CAPSULE DR	N
lipase/protease/amylase	ULTRASE MT 12	CAPSULE DR	N
lipase/protease/amylase	ULTRASE MT 18	CAPSULE DR	N
lipase/protease/amylase	ULTRASE MT 20	CAPSULE DR	N
lipase/protease/amylase	ULTRASE MT 6	CAPSULE DR	N
lipase/protease/amylase	ZENPEP	CAPSULE DR	N
lipase/protease/amylase	PANCRELIPASE	TABLET	N
lipase/protease/amylase	VIOKASE	TABLET	N

**Appendix 2: Medline Search Strategy**

Database(s): Ovid MEDLINE(R) 1946 to July Week 1 2018

Search Strategy:

#	Searches	Results	
1	Pancrelipase/	314	
2	creon.mp.	78	
3	pertzye.mp.	2	
4	ultrase.mp.	2	
5	ultrase MT 20.mp.	1	
6	ultrase MT 6.mp.	0	
7	zenpep.mp.	10	
8	viokase.mp. or Pancrelipase/	332	
9	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8	372	
10	limit 9 to (english language and humans and yr="2017 -Current")		6

### Appendix 3: Pancreatic Enzyme Formulations

**Table 1. Pancreatic Enzyme Replacement Therapy Products**

<b>Name</b>	<b>Type</b>	<b>Indications</b>
<b>Creon<sup>®1</sup></b>	Delayed release/enteric coated	Treatment of exocrine pancreatic insufficiency due to cystic fibrosis, chronic pancreatitis, pancreatectomy, or other conditions
<b>Pancreaze<sup>®2</sup></b>	Delayed release/enteric coated	Treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions
<b>Pancrelipase<sup>3</sup></b>	Delayed release/enteric coated	Treatment of steatorrhea secondary to pancreatic insufficiency such as cystic fibrosis or chronic alcoholic pancreatitis
<b>Pertyze<sup>®4</sup></b>	Delayed release/enteric coated	Treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions
<b>Ultrase<sup>®5</sup></b>	Delayed release/enteric coated	Indicated for patients with partial or complete exocrine pancreatic insufficiency
<b>Ultresa<sup>®6</sup></b>	Delayed release/enteric coated	Treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions
<b>Viokace<sup>®7</sup></b>	Non-enteric coated	For use in combination with a proton pump inhibitor, is indicated in adults for the treatment of exocrine pancreatic insufficiency due to chronic pancreatitis or pancreatectomy
<b>Zenpep<sup>®8</sup></b>	Delayed release/enteric coated	Treatment of exocrine pancreatic insufficiency due to cystic fibrosis, or other conditions