Reference number(s)
3156-A

This document applies to the following:

Formulary	Applies
Advanced Control (ACF)	☐
Advanced Control Formulary Chart (ACFC)	☐
Advanced Control – Choice (ACCF)	☐
Basic Control (BC)	☐
Basic Control Chart (BCC)	☐
Standard Control (SF)	☐
Standard Control Formulary Chart (SFC)	☐
Standard Control – Choice (SCCF)	☐

Formulary	Applies
Value (VF)	☑
Value Formulary Chart (VFC)	☐
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Aetna-Fully Insured Advanced Control Formulary (Aetna FI ACF)	☐
Aetna Fully Insured Advanced Control Formulary Chart (Aetna FI ACFC)	☐
Aetna Fully Insured Standard Opt-Out (Aetna FI SOO)	☐

Medical Necessity Criteria
Creon, Pertzye, Viokace

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Creon	pancrelipase
Pertzye	pancrelipase
Viokace	pancrelipase

Indications

FDA-approved Indications

Creon, Pertzye

These products are indicated for the treatment of exocrine pancreatic insufficiency in adult and pediatric patients.

Viokace

Viokace, in combination with a proton pump inhibitor, is indicated for the treatment of exocrine pancreatic insufficiency due to chronic pancreatitis or pancreatectomy in adults.

Coverage Criteria

Exocrine Pancreatic Insufficiency

Authorization may be granted when the requested drug is being prescribed for the treatment of exocrine pancreatic insufficiency when ALL of the following criteria are met:

- The patient has experienced a documented intolerance to or has a clinical reason to avoid ALL of the preferred products: Pancreaze and Zenpep. [ACTION REQUIRED: Documentation is required for approval.]
- If the request is for Viokace, the patient will take Viokace in combination with a proton pump inhibitor (PPI).

Continuation of Therapy

All Indications (Pediatric)

Authorization may be granted for the requested drug when the following criteria is met:

- The patient is less than 18 years of age.

Exocrine Pancreatic Insufficiency

All patients (including new patients) requesting authorization for continuation of therapy must meet ALL requirements in the coverage criteria section.

Duration of Approval (DOA)

- 3156-A: DOA: 12 months

References

1. Creon [package insert]. North Chicago, IL: AbbVie Inc.; February 2024.
2. Pertzye [package insert]. Bethlehem, PA: Digestive Care, Inc.; February 2024.
3. Viokace [package insert]. Bridgewater, NJ: Aimmune Therapeutics, Inc.; July 2025.
4. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2025. https://online.lexi.com. Accessed September 9, 2025.
5. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 09/09/2025).