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
Pancreaze, 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
Pancreaze	pancrelipase
Pertzye	pancrelipase
Viokace	pancrelipase

Indications

FDA-approved Indications

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Pancreaze, 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: Creon 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

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References

1. Pancreaze [package insert]. Campbell, CA: Vivus LLC; February 2024.
2. Pertzye [package insert]. Bethlehem, PA: Digestive Care, Inc.; February 2024.
3. Viokace [package insert]. Bridgewater, NJ: Aimmune Therapeutics, Inc.; February 2024.
4. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed September 3, 2024.
5. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 09/03/2024).

Document History

Written by: UM Development (MAC)

Date Written: 08/2019

Revised: (MAC) 09/2019 (added Pancreaze, Pertzye as targeted drugs), 09/2020 (updated document name/title); (JK) 09/2021 (updated document title); (VLS) 09/2022 (no clinical changes); (SS) 09/2023 (removed Viokace from prereqs and added to targeting; removed Zenpep from targeting and added to prereqs), (SS) 09/2023 (annual review - no clinical changes), (MRS) 09/2024 (no clinical changes)

Reviewed: Medical Affairs: (EPA) 08/2019, (ME) 09/2019, (CHART) 09/30/2021, 09/22/2022, (AN) 09/2023, (CHART) 09/28/2023, 09/26/2024

External Review: 10/2019, 12/2020, 12/2021, 12/2022, 10/2023, 12/2023, 12/2024

CRITERIA FOR APPROVAL

1	Is the patient less than 18 years of age? [If Yes, then go to 2. If No, then go to 3.]	Yes	No
2	Is the request for continuation of therapy? [If Yes, then no further questions. If No, then go to 3.]	Yes	No
3	Is the requested drug being prescribed for the treatment of exocrine pancreatic insufficiency? [If Yes, then go to 4. If No, then no further questions.]	Yes	No
4	Is this request for Viokace? [If Yes, then go to 5. If No, then go to 6.]	Yes	No

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5	Will the patient take Viokace in combination with a proton pump inhibitor (PPI)? [If Yes, then go to 6. If No, then no further questions.]	Yes	No
6	Has the patient experienced a documented intolerance to or has a clinical reason to avoid ALL of the preferred products: Creon and Zenpep? ACTION REQUIRED: If yes, then documentation is required for approval. Please document the intolerance to or clinical reason to avoid BOTH Creon and Zenpep: _____ [If Yes, then go to 7. If No, then no further questions.]	Yes	No
7	Has documentation of the patient's intolerance to or clinical reason to avoid BOTH Creon and Zenpep been submitted to CVS Health? [No further questions] Tech Note: Documentation of the patient's intolerance to or clinical reason to avoid BOTH Creon and Zenpep is required for approval.	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Go to 3	
2.	Approve, 12 Months	Go to 3	
3.	Go to 4	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use is for exocrine pancreatic insufficiency. Your plan does not cover this drug for your health condition that your doctor told us you have. This drug is not a preferred drug on your plan. The preferred drugs for your plan are: Creon and Zenpep. Your doctor may need to get approval from your plan for preferred drugs. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]

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4.	Go to 5	Go to 6	
5.	Go to 6	Deny	Your plan only covers this drug if you will be taking it with a proton pump inhibitor (PPI). We have denied your request because you are not (or will not be) taking it with a proton pump inhibitor (PPI). This drug is not a preferred drug on your plan. The preferred drugs for your plan are: Creon and Zenpep. Your doctor may need to get approval from your plan for preferred drugs. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Concurrent therapy]
6.	Go to 7	Deny	Your plan only covers this drug when you meet one of these options: A) You have tried other drugs your plan covers (preferred drugs), and they did not work well for you, or B) Your doctor gives us a medical reason you cannot take those other drugs. For your plan, you may need to try 2 preferred drugs. We have denied your request because you do not meet any of these conditions. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. The preferred drugs for your plan are: Creon and Zenpep. Your doctor may need to get approval from your plan for preferred drugs. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Non-formulary/non-preferred]
7.	Approve, 12 Months	Deny	Your plan only covers this drug when the reason why all of the preferred drugs did not work well for you or why you cannot take all of the preferred drugs is sent to us. Your doctor needs to send us the reason why you are unable to take all of the preferred drugs. We have denied your request because we did not receive the

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			reason. This drug is not a preferred drug on your plan. The preferred drugs for your plan are: Creon and Zenpep. Your doctor may need to get approval from your plan for preferred drugs. Your doctor told us that you have tried the preferred drugs or have a reason to avoid them. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Documentation]

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