These criteria apply to the following:			
✓ ACF	✓ BF	☐ MMT	✓ Aetna FI ACF
✓ ACFC	☐ VF	☐ Marketplace (MF)	✓ Aetna FI ACFC
☐ SF	☐ VFC	☐ Aetna SG ACA (Aetna Health Exchanges)	☐ Aetna FI SOO
✓ SFC		☐ Aetna IVL	

MEDICAL NECESSITY CRITERIA

DRUG CLASS	MEDICAL NECESSITY CRITERIA
BRAND NAME* (generic)	PANCREAZE (pancrelipase) PERTZYE (pancrelipase)
Status: CVS Caremark Criteria	
Type: Medical Necessity Criteria	*Ref # 3309-A*

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS

Pancreaze
Pancreaze (pancrelipase) is indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions.

Pertzye
Pertzye (pancrelipase) is indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient is less than 18 years of age
  AND
- The request is for the continuation of therapy

OR

- The requested drug is being prescribed for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions
  AND
- The patient has experienced a documented intolerance to or has a clinical reason to avoid ALL of the preferred products: Creon, Viokace, and Zenpep

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The intent of this SF ACF Formulary Exception program is to confirm the appropriate coverage of the non-formulary prescription medications, Pancreaze (pancrelipase) and Pertzye (pancrelipase) for patients. These medications are indicated for the treatment of exocrine pancreatic

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✓ ACFC	☐ VF	☐ Marketplace (MF)	✓ Aetna FI ACFC
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✓ SFC		☐ Aetna IVL	

insufficiency due to cystic fibrosis or other conditions.[1-2] Pancrelipase is not effective in the treatment of functional digestive disorders unrelated to pancreatic insufficiency.[3]

If the patient is less than 18 years of age, and the patient is continuing therapy, then the request will be approved due to sensitivity for pediatric patients with cystic fibrosis. If the requested drug is being prescribed for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions, and the patient has experienced a documented intolerance to or has a clinical reason to avoid ALL of the preferred products: Creon, Viokace and Zenpep, then the request will be approved.

REFERENCES

1. Pancreaze [package insert]. Campbell, CA: Vivus, Inc.; October 2018.
2. Pertzye [package insert]. Bethlehem, PA: Digestive Care, Inc.; March 2020.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed September 2020.
4. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed September 201920.

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External Review: 12/2020

CRITERIA FOR APPROVAL

1	Is the patient less than 18 years of age? [If no, then skip to question 3.]	Yes	No
2	Is the request for continuation of therapy? [If yes, then no further questions.]	Yes	No
3	Is the requested drug being prescribed for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions? [If no, then no further questions.]	Yes	No
4	Has the patient experienced a documented intolerance to or has a clinical reason to avoid ALL of the preferred products:Creon, Viokace, and Zenpep? [If yes, then documentation is required for approval.]	Yes	No

Drug Name: Creon Clinical Rationale_____

Drug Name: Viokace Clinical Rationale_____

These criteria apply to the following:			
✓ ACF	✓ BF	☐ MMT	✓ Aetna FI ACF
✓ ACFC	☐ VF	☐ Marketplace (MF)	✓ Aetna FI ACFC
☐ SF	☐ VFC	☐ Aetna SG ACA (Aetna Health Exchanges)	☐ Aetna FI SOO
✓ SFC		☐ Aetna IVL	

Drug Name: Zenpep Clinical Rationale_____

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Go to 3	
2.	Approve, 12 months	Go to 3	
3.	Go to 4	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have pancreatic insufficiency due to cystic fibrosis or other conditions. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
4.	Approve, 12 months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when there is a reason you are unable to take ALL of the following: -Creon -Viokace -Zenpep Your request has been denied based on the information we have. [Short Description: No reason to avoid ALL preferred products]