

Initial Prior Authorization

Pancrelipase

Pancreatic Enzymes

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 |
| Pancreaze | pancrelipase |
| Pertzye | pancrelipase |
| Viokace | pancrelipase |
| Zenpep | pancrelipase |

Indications

FDA-approved Indications

Creon, Pancreaze, Pertzye, Zenpep

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.

| |
|---------------------|
| Reference number(s) |
| 3134-A |

Coverage Criteria

Exocrine Pancreatic Insufficiency

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

- If the request is for Viokace, the patient will take Viokace in combination with a proton pump inhibitor (PPI).

Duration of Approval (DOA)

- 3134-A: DOA: 12 months

References

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

Document History

Written by: UM Development (KC)

Date Written: 07/2019

Revised: (KC) 09/2019 (no clinical changes), (MAC) 09/2020 (no clinical changes), (JK) 09/2021 (no clinical changes), (VLS) 09/2022 (no clinical changes), (SS) 09/2023 (no clinical changes), (MRS) 09/2024 (no clinical changes)

Reviewed: Medical Affairs (CHART) 08/08/19, 09/26/19, 09/24/20, 09/30/21, 09/22/2022, 09/28/2023, 09/26/2024

External Review: 08/2019, 12/2019, 12/2020, 12/2021, 12/2022, 12/2023, 12/2024

CRITERIA FOR APPROVAL

- | | | | |
|---|---|-----|----|
| 1 | Is the requested drug being prescribed for the treatment of exocrine pancreatic insufficiency? [If Yes, then go to 2. If No, then no further questions.] | Yes | No |
| 2 | Is this request for Viokace? [If Yes, then go to 3. If No, then no further questions.] | Yes | No |
| 3 | Will the patient take Viokace in combination with a proton pump inhibitor (PPI)? [No further questions] | Yes | No |

| Mapping Instructions | | | |
|----------------------|--------------------|--------------------|---|
| | Yes | No | DENIAL REASONS |
| 1. | Go to 2 | Deny | <p>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. 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.</p> <p>[Short Description: Diagnosis]</p> |
| 2. | Go to 3 | Approve, 12 Months | |
| 3. | Approve, 12 Months | Deny | <p>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). 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.</p> |

| |
|---------------------|
| Reference number(s) |
| 3134-A |

| | | | |
|--|--|--|---|
| | | | [Short Description: Concurrent therapy] |
|--|--|--|---|