

MTF Formulary Management
Pancreatic Enzyme Replacement Therapy (PERT)
 Defense Health Agency Pharmacy Operations Division

Bottom Line:

- Creon remains BCF and is now the preferred PERT product. All other PERT products are non-preferred and now require prior authorization.
- Zenpep, Viokace, and Pancreaze are now nonformulary.
- Step therapy requires a trial of Creon in all new and current users of a PERT.
- MTFs should maximize use of Creon, by switching patients from the non-preferred product to Creon. Switching should be done by matching lipase units and adjusting as needed every 1-2 weeks.
- The majority of PERT usage in DoD is for patients older than 60 years.

Uniform Formulary Decision: The Director, DHA, approved the recommendations from the May 2018 DoD P&T Committee meeting on August 6, 2018. Implementation will occur on November 7, 2018.

Uniform Formulary (UF) Agents		Nonformulary (NF) Agents
BCF drugs – MTFs <u>must</u> have on formulary	MTFs <u>may</u> have on formulary	MTFs <u>must not</u> have on formulary
<u>Step Preferred:**</u> <ul style="list-style-type: none"> • Creon 	<u>Non-step-preferred:</u> <ul style="list-style-type: none"> • Viokace tablet 	<u>Non-step-preferred:</u> <ul style="list-style-type: none"> • Pancreaze • Pertzye • Ultresa (discontinued per manufacturer) • Zenpep
** Step therapy applies to ALL (new and current) users of the PERT products; no grandfathering applies for any user. See detailed criteria below.		

Clinical Summary

- Pancreatic Enzyme Replacement Therapy (PERT) is used to treat exocrine pancreatic insufficiency due to cystic fibrosis, chronic pancreatitis, pancreatectomy, or other conditions (e.g., total gastrectomy, celiac disease).
- The PERT products all contain porcine-derived amylases, lipases, and proteases.
- Advantages of Creon include that it has the greatest number of FDA-approved indications and is formulated in five dosages including higher strengths (lipase enzyme units of 24k and 36k). Dosing is available for breast/bottle-fed infants under 1 year of age.
- Viokace is the only PERT without an indication for treating exocrine pancreatic insufficiency due to cystic fibrosis and is not approved for use in children. It is formulated as an uncoated tablet and requires administration with a proton pump inhibitor (PPI) to prevent degradation in the stomach.
 - Reserve Viokace for patients needing uncoated tablets due to actual or suspected dissolution issues with the enteric coating found in the other capsule formulations.
- Pertzye is the only product with gastrostomy (G)-tube administration information contained in the package insert; however, instructions are available for G-tube administration with Creon and Viokace.
- **The PERTs are not interchangeable at the pharmacy, and new prescriptions are needed when switching between products.** For switching, consider starting Creon with the dosage containing a similar

amount of lipase enzyme as the current PERT, then adjust the dose based on the patient's response. Recognize that it may take 1-2 weeks for the full dose response to be seen.

Manual Prior Authorization Issues for PERTs

- **Creon does not require prior authorization. Switching patients from Zenpep, Viokace, or Pancreaze will not require additional paperwork.**
- All **new and current users** of Pancreaze, Pertzye, Zenpep, or Viokace require a trial of Creon first, unless they meet the following PA criteria:
 - Patient has failed Creon with an adequate trial of at least 2 dose adjustments over at least 4 weeks OR
 - Patient is ≤ 2 years old and a sufficient trial of Creon was unsuccessful
- For patients using the TRICARE Mail Order pharmacy or Retail Network, the Creon co-pay has been lowered from the Tier 2 co-pay to the generic Tier 1 co-pay.

References

- DoD P&T Committee minutes: <http://www.health.mil/PandT>
- Current/future drug classes under review by the DoD P&T Committee: <http://www.health.mil/PandT> (scroll down to DoD P&T Committee Meeting Schedule)
- TRICARE Formulary Search Tool: <http://www.health.mil/formulary>
- Prior Authorization/Medical Necessity forms: See Formulary Search Tool above.
- Formulary Management Documents (including this one) available at: <http://www.health.mil/DoDPTResources>
- Point of contact for additional information: dha.jbsa.pharmacy.list.poduf@mail.mil

PERT Price Comparison at MTF	
Drug	MTF Cost/Month (May 2018)
Basic Core Formulary	
Creon	\$ = Most Cost-Effective
Uniform Formulary	
Viokace	\$\$ = Less Cost-Effective
Nonformulary	
Pancreaze	\$\$\$\$ = Least Cost-Effective
Pertzye	
Ultresa	
Zenpep	
Legend:	
\$ = "Most Cost-Effective" represents Rx's with the <u>lowest cost</u> and best clinical efficacy	
\$\$ = "Less Cost-Effective" represents <u>higher cost</u> Rx's with similar clinical efficacy	
\$\$\$ = "Less Cost-Effective" represents <u>next higher cost</u> Rx's with similar clinical efficacy	
\$\$\$\$ = "Least Cost-Effective" represents Rx's with the <u>highest cost</u> with similar clinical efficacy	