

## **DoD P&T Committee Evaluation of the PEC Class: PANCREATIC ENZYME**

**AGENTS PEC Sub Class: NONE are**

**Hereinafter Referred to as “Class”**

**And medications in the Pharmaceutical Agents Table are**

**Hereinafter Referred to as “Agents”**

**NOTE: The DoD Pharmacy and Therapeutics (P&T) Committee will consider Uniform Formulary Blanket Purchase Agreement (UF BPA) price quotes and Uniform Formulary Voluntary Agreement for TRICARE Retail Pharmacy Refunds (UF VARR) quotes that are contingent upon the number of agents selected for the Uniform Formulary (UF). The Condition Sets and procedures for submitting UF BPA and UF VARR quotes are outlined in the UF BPA Price Quote template (see Appendix A), the UF VARR Quote template (see Appendix A) and under the "UF Price and Refunds Quotes" section below:**

### **Drug Class Description**

The DoD Pharmacy and Therapeutics (P&T) Committee intends to evaluate the pharmaceutical agents in this class at the upcoming meeting:

#### **Pharmaceutical Agents:**

<b>CREON</b>
<b>PANCREAZE</b>
<b>PANCRELIPASE 5,000</b>
<b>PERTZYE</b>
<b>ULTRESA</b>
<b>VIOKACE</b>
<b>VIOKASE</b>
<b>ZENPEP</b>

### **Uniform Formulary Considerations**

In accordance with 32 CFR 199.21, the P&T Committee will consider the relative clinical effectiveness and relative cost effectiveness of this class in recommending a cost share tier classification (i.e., generic, formulary, or non-formulary) for each agent. There is no minimum or maximum number of agents that may be placed in a given cost share tier classification, though you are instructed to submit multiple quotes based on different conditions (See NOTE above and UF Price and Refunds Quotes section below). Although all the formulations (dosage forms and/or strengths) for a given agent would typically be recommended for the same cost share tier classification, the P&T Committee reserves the right to recommend different cost share tier classifications for a particular formulation of a given agent if the Committee finds significant differences in the clinical effectiveness or cost effectiveness between formulations of a given agent.

### **Basic Core Formulary (BCF) and Extended Core Formulary (ECF) Considerations**

All agents recommended for the generic or formulary cost share tier on the Uniform Formulary will be considered for inclusion on the BCF/ECF. The DoD P&T Committee intentions for the number of BCF/ECF agents in each class and subclass are listed below.

### **UF BPA and UF VARR Quotes**

At this time, DoD will accept price quotes using two different instruments: the UF BPA price quote and the UF VARR quote. Pharmaceutical companies must use the UF BPA price quote for prices that will apply to MTFs and the Mail Order Pharmacy. Pharmaceutical companies must use the UF VARR quote for refunds that will apply to pharmaceuticals dispensed by pharmacies in the Retail Pharmacy Network. While generally similar, each instrument has specific instructions and different submission details.

#### Price Quotes for MTFs and Mail Order Pharmacy

##### Price Quote Instrument: **UF BPA**

The item descriptions and NDC numbers for this class that are covered by FSS contracts are listed in the class utilization dataset. A UF BPA price quote for this Class must include all the NDCs that are included on the FSS contract, **unless a request to exclude a specific NDC is approved by the TMA contracting officer in writing** as described in the "Instructions for Submitting a BPA Price Quote" on the **Uniform Formulary Price and Refund Quote Information Page**.

The prices submitted in the UF BPA price quotes will be contingent upon the number of agents selected for the UF and BCF/ECF. Pharmaceutical companies that submit UF BPA price quotes **must submit a separate, complete quote for each NDC in the class associated UF BPA Appendix**. This will ensure that a company will have a valid price quote for whatever number of agents are recommended for inclusion on the UF and/or BCF/ECF.

**The DoD P&T Committee will not accept UF BPA price quotes that are contingent upon market shares.**

The DoD reserves the right to exclude specific formulations of a given class or agent from a submitted UF BPA quote based on the recommendations of the P&T Committee and the final decision of the Director, TMA, regarding the UF and BCF/ECF for specific formulations of a given class or agent.

The establishment of a UF BPA with a pharmaceutical company for a generic (multi-source) pharmaceutical agent **does not** establish that pharmaceutical company as the sole source of supply for the pharmaceutical agent. However, in the event of existing Joint DoD/VA contracts, UF BPA quotes will not be accepted for generic (multi-source) pharmaceutical agents.

#### Price Quotes for the Retail Pharmacy Network

##### Price Quote Instrument: **UF VARR**

The item descriptions and NDC numbers for this class that were utilized in the Retail Pharmacy Network for the last 12 months are listed in the class utilization dataset. A UF VARR quote for an agent is required to include all the NDCs that are included in the FSS NDC list included in the dataset. The DoD will make no attempt to force participating retail pharmacies to dispense specific NDCs.

The proposed refunds submitted in the UF VARR quotes will be contingent upon the number of agents selected for the UF. Pharmaceutical companies that submit UF VARR quotes **must submit a separate VARR quote for each NDC in the class associated UF VARR Appendix**. This will ensure that a company will have a valid price quote for whatever number of agents are recommended for inclusion on the UF.

**The DoD P&T Committee will not accept UF VARR quotes that are contingent upon market shares.**

The DoD reserves the right to exclude specific formulations of a given class or agent from a submitted UF VARR quote based on the recommendations of the P&T Committee and the final decision of the Director, TMA, regarding the UF and BCF/ECF for specific formulations of a given agent.

UF VARR quotes will not be accepted for generic (multi-source) pharmaceutical agents.

## **Utilization Data and Determining the Cost of the Class**

The **Uniform Formulary Price Quote Information Page** outlines the general approach for determining the cost of this class. Historical utilization data and an example of how an overall weighted average cost per day of therapy may be determined are provided in the utilization dataset.

For the upcoming meeting, it has been determined that none of the agents in the class has an existing price agreement that can be used for determining the cost of a class during the upcoming UF evaluation.

The Evaluation Price for this class will be:

- **For the MTF and Mail dispensing venues** - The lower of:
  - A UF BPA price quote
  - Big 4 FSS price as listed on the first day of the month preceding the DoD P&T meeting.
- **For the Retail dispensing venue**- The lower of:
  - UF VARR calculated refund
  - Absent a UF VARR Quote, the current price as of the first day of the month preceding the DoD P&T meeting.
  - If TMA signs a UF VARR higher than the FCP, this does not waive any right of the Department of Defense under 10 U.S.C. 1074g(f).