

DoD P&T Committee Evaluation

DoD P&T Class: PULMONARY ARTERIAL HYPERTENSION

(hereinafter referred to as "Class" and medications in the Pharmaceutical Agents table referred to as "Agents")

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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 / Pharmaceutical Agents:

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

ADCIRCA	LETAIRIS	ORENITRAM ER
REVATIO	OPSUMIT	TYVASO
ADEMPAS	TRACLEER	VENTAVIS

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 DHA 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**

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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 agent(s) is/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, DHA, 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 agent(s) is/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, DHA, 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 DHA 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).

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UF BPA Appendix for the **February 2015** DoD P&T Meeting

Uniform Formulary Price Quotes and Uniform Formulary Blanket Purchase Agreements (BPA)

The following Condition Sets, as authorized at each listed UF Drug Class Page, identify the conditions under which UF BPA price quotes are to be submitted by the Company.

Medications placed on the Uniform Formulary but not BCF or ECF are available for the local Military Treatment Facility P&T to decide whether to place on their individual formulary.

The Company must submit a separate, complete UF BPA price quote for each NDC (enter in table below*) that applies to the Company's pharmaceutical agent(s) in a given drug class.

Grandfathering: a prior authorization process would require all new patients to complete an adequate trial of the step-preferred agent(s) before a non-step-preferred agent is provided to a new user. Unless otherwise noted, patients must have tried an agent in the class in the previous 180 days in order to be excluded from the prior authorization process.

No grandfathering: a prior authorization process would require all patients, regardless of past medication history to complete an adequate trial of the step-preferred agent(s) before a non-step-preferred agent is provided to a user.

Grandfathering unstipulated: DHA reserves the right to choose the grandfathering or no-grandfathering of some or all agents based the total price/clinical evaluations after quotes have been submitted and in the best interests of the Government.

NDC*	Drug Name	Strength	Dosage Form	Package Size

DoD P&T Class: PULMONARY ARTERIAL HYPERTENSION				
Class Note(s): The PAH drug class is divided into several subclasses.				
Step Therapy Addendum: Within the PDE-5 and soluble guanylate cyclase stimulators, the Prostacyclins, and the ERA subclasses, there may be a step-preferred drug within each subclass. The ECF drug will be selected from among the subclasses.				
Condition Set #	Category **	One of (X) number of brand agents	Military Treatment Facility & Mail Order	
			Price per Unit of Measure (each, gram, mL) to 4 decimal places	Price Per NDC to 4 decimal places
PDE-5 AGENTS				
Military Treatment Facility & Mail 152PHPEG1ECAS1M	Extended Core Formulary After Step Therapy	1 or more	\$	\$
Military Treatment Facility & Mail 152PHPEG1ECBS1X	Extended Core Formulary Before Step Therapy	1	\$	\$
SOLUABLE GUANYLATE CYCLASE AGENTS				
Military Treatment Facility & Mail 152PHGCG1ECAS1M	Uniform Formulary & Tier 2 After Step Therapy	1 or more	\$	\$
Military Treatment Facility & Mail 152PHGCG1ECBS1X	Uniform Formulary & Tier 2 Before Step Therapy	1	\$	\$
PROSTACYCLIN AGENTS				
Military Treatment Facility & Mail 152PHPTG1UFAS1M	Uniform Formulary & Tier 2 After Step	1 or more	\$	\$

	Therapy			
Military Treatment Facility & Mail 152PHPTG1UFBS1X	Uniform Formulary & Tier 2 Before Step Therapy	1	\$	\$
Military Treatment Facility & Mail 152PHPTG0UFNS1M	Uniform Formulary & Tier 2 No Step Therapy	1 or more	\$	\$
ERA AGENTS				
Military Treatment Facility & MTF 152PHENU1UFAS1M	Uniform Formulary & Tier 2 After Step Therapy	1 or more	\$	\$
Military Treatment Facility & MTF 152PHENU1UFBS1X	Uniform Formulary & Tier 2 Before Step Therapy	1	\$	\$
Military Treatment Facility & MTF 152PHENU0UFNS1M	Uniform Formulary & Tier 2 No Step Therapy	1 or more	\$	\$

** Only one price per category may be submitted.

UF VARR Appendix for the February 2015 DoD P&T Meeting

Condition Sets for Uniform Formulary Voluntary Agreements for TRICARE Retail Refunds (UF-VARR)

The following Condition Sets, as authorized at each listed UF Drug Class Page, identify the conditions under which UF-VARR quotes are to be submitted by the Company.

The Company must submit a separate, complete UF-VARR quote for each Condition Set that applies to the Company's pharmaceutical agents in a given drug class. The Company must record the Condition Set # that applies to a given UF-VARR quote in the appropriate blank on Table 1, Uniform Formulary Refund Quote.

The refund quoted will apply to the resulting UF-VARR if the quoted pharmaceutical agent is selected for inclusion on the UF in no worse than the formulary (2nd) cost share tier. The refund quoted is not contingent on the quoted pharmaceutical agent being selected for inclusion on the BCF or ECF.

Grandfathering: a prior authorization process would require all new patients to complete an adequate trial of the step-preferred agent(s) before a non-step-preferred agent is provided to a new user. Unless otherwise noted, patients must have tried an agent in the class in the previous 180 days in order to be excluded from the prior authorization process.

No grandfathering: a prior authorization process, would require all patients, regardless of past medication history to complete an adequate trial of the step-preferred agent(s) before a non-step-preferred agent is provided to a user.

Grandfathering unstipulated: DHA reserves the right to choose the grandfathering or no-grandfathering of some or all agents based the total price/clinical evaluations after quotes have been submitted and in the best interests of the Government.

NDC	Drug Name	Strength	Dosage Form	Package Size

DoD P&T Class: PULMONARY ARTERIAL HYPERTENSION							
Class Note(s): The PAH drug class is divided into several subclasses.							
Step Therapy Addendum: Within the PDE-5 and soluble guanylate cyclase stimulators, the Prostacyclins, and ERA subclasses, there may be a step-preferred drug within each subclass.							
Condition Set #	Category	One of (X) Number of brand agents	Most recent Annual Non-Federal Average Manufacturer's Price* (Non-FAMP) per FCP Package Size. CHANGES ANNUALLY (\$)	Current Annual Federal Ceiling Price* (FCP) per FCP Package Size. CHANGES ANNUALLY (\$)	Standard Refund per FCP Package Size CHANGES ANNUALLY ((NFAMP – FCP)/NFAMP) *100= X% (%)	Additional Refund per FCP Package Size Percentage is Static NFAMP *(Y%) (%)	Total Offered Retail Refund per FCP Package Size CHANGES ANNUALLY (((NFAMP – FCP)/NFAMP) *100= X%) + (NFAMP *(Y%)) = Total% (%)
PDE-5 AGENTS							
152PHPEG1T2AS1M	Tier 2 After Step Therapy	1 or more	\$	\$	%	%	%

152PHPEG1T2BS1X	Tier 2 Before Step Therapy	1	\$	\$	%	%	%
SOLUABLE GUANYLATE CYCLASE AGENTS							
152PHGCG1T2AS1M	Tier 2 After Step Therapy	1 or more	\$	\$	%	%	%
152PHGCG1T2BS1X	Tier 2 Before Step Therapy	1	\$	\$	%	%	%
PROSTACYCLIN AGENTS							
152PHPTG1T2AS1M	Tier 2 After Step Therapy	1 or more	\$	\$	%	%	%
152PHPTG1T2BS1X	Tier 2 Before Step Therapy	1	\$	\$	%	%	%
152PHPTG0T2NS1M	Tier 2 No Step Therapy	1 or more	\$	\$	%	%	%
ERA AGENTS							
152PHENU1T2AS1M	Tier 2 After Step Therapy	1 or more	\$	\$	%	%	%
152PHENU1T2BS1X	Tier 2 Before Step Therapy	1	\$	\$	%	%	%
152PHENU0T2NS1M	Tier 2 No Step Therapy	1 or more	\$	\$	%	%	%