

Meeting Minutes for UF BPA/VARR

Industry Teleforum FY15Q1

November 20, 2014 10:30 CST

1. Attendance:

LTC Robert Conrad – Deputy Chief, Operations Management Branch – Industry Liaison, DHA Pharmacy Operations Division – San Antonio

Michael Bennett - PASS IT Team - Team Lead - Web Developer

Matthew Halbe – Jr. Contract Analyst – DHA Contract Management

Bruce Mitterer – Contracting Officer – DHA Contract Management

2. POD Website: http://pec.ha.osd.mil/pt_review_Feb2015.php

Make sure all instructions are read carefully, follow the steps, print out all the applicable documents, and submit by the due date listed.

3. Drug Classes:

1. Oral Oncological Agents/Prostate I & II
2. Transmucosal Immediate Release Fentanyl
3. Pulmonary Arterial Hypertension
4. Newly Approved Drug
 1. Zontivity
 2. Hetlioz
 3. Belsomra – Solicitation Cancelled
 4. Jardiance
 5. Esomeprazole Strontium
 6. Strendra

4. Quote Submissions:

Note there are a few changes to the solicitation process.

1. All original quotes and email duplicates are due on Dec 31, 2014 by 1:00 PM EST (11:00 AM MST). Suppliers are encouraged to submit their quotes early. For overnight delivery, it is suggested suppliers use FedEx Priority mail.
2. Consolidation of solicitation documents/appendices on the POD website. Note: For the three drug classes on POD solicitation webpage (Oral Oncological Agents/Prostate 1 & 2,

Transmucosal Immediate Release Fentanyl, Pulmonary Arterial Hypertension) when loading documents, first few instruction pages are for INFORMATIONAL PURPOSES ONLY AND ARE NOT PART OF THE UF BPA AND VARR. Offerors should separate from the BPA and VARR appendixes.

3. New Contracting Point of Contact:

Matthew Halbe
 Jr. Contract Analyst
matthew.halbe.ctr@dha.mil
 Ph: 303-676-3529

Lessons Learned: Responsiveness:

It is important that suppliers respect the process that is in place by carefully reading the BPA, VARR and all instructions that accommodate it to ensure the quoting procedure is properly followed.

Past Reasons for non-responsive:

Non-Responsive Reason	Citation
Company does not hold an FSS contract, or the FSS contract has expired	UF BPA Paragraph 10 “The company must have an existing FSS Contract for any pharmaceutical agent(s) quoted in this UFBPA at the time the quote is submitted, and at the time the UFBPA is executed”
Signed BPA terms and conditions is not submitted on time	http://pec.ha.osd.mil/pt_review_Feb2015.php
Ensure calculations are correct and to four decimal places	BPA Paragraph 10 Line 13
Price per dosage unit will be the same for all package sizes	BPA Paragraph 8.b

Company name on the BPA will be the company that receives the BPA, and must match the FSS. No subsidiaries, affiliates, or DBA’s are allowed.

5. E-Bidding system (Testing Phase)

The new e-bidding system is currently in its testing phase. For any supplier who wish to use it to gain familiarity and provide feedback, please contact LTC Robert Conrad (Robert.Conrad@dha.mil). This is **not** part of the current solicitation process and will only be used for testing purposes.

6. Questions & Answers:

Q: As December 31 falls in the middle of winter break, many executives that are authorized to provide the signatures needed will not be in the office. Can you postpone the due date till the middle of January?

A: We have purposely provided additional time for this quoting process (6 weeks instead of the usual 4) for the sole reason to provide each company with ample time to get their quotes in on time. We strongly encourage our bidders to try and submit their bid early.

Q: In the VARR Appendix, it calls for the current Federal Ceiling Price which changes annually. Since the quotes are due at the end of the calendar year, which FCP pricing are we using, 2014 or 2015 prices?

A: Defer on a response during conference call. A response will be posted later.

A: ANSWER REVISED 12/04/2014: Current FCP pricing in effect the date the quote is submitted.

Q: Why is DoD reviewing anti-androgen class when all agents are available as generics? Also, the DLA just awarded a national contract for bicalutamide (Casodex generic) in early Sept. 2014.

A: The DoD P&T Committee has not previously reviewed this sub-class within the Oral Oncology Class. The generic Casodex has been sporadically available forcing pharmacies to purchase brand name Casodex. The Brand to Generic requirement has been overridden in some instances where generic availability has been problematic.

Q: PAH ERA utilization has been historically low at the MTF Point of Service. Are there plans to shift utilization to this POS?

A: No, there are no plans for shifting utilization to any particular point of service.

Q: The class is titled "Oral Oncological Agents / Prostate I & II". Which drugs are I and which are II? Are I drugs and II drugs being treated as 2 completely different drug classes?

A: Prostate I: Nilandron, Casodex, and Eulexin Prostate II: Xtandi, Zytiga

The Prostate I and II subclasses are being treated as two separate subclasses. A BCF agent may be selected from the Prostate I subclass and step-therapy may apply to the Prostate II subclass.

Q: Under the section titled "Data and Determining the Cost of the Class", it is stated 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." Xtandi® (enzalutamide) capsules has a BIG4 price. Why can't the BIG4 be used in the "Evaluation Price" process? For full prescribing information please visit www.xtandihcp.com.

A: If a quote is not submitted, and if there is a permanent BIG 4 or permanent FSS prices, the BIG 4 or FSS prices will be used for the cost effectiveness evaluation. Offerors may submit quotes at or below the BIG 4 or FSS prices.

Q: Under the "UF BPA appendix", within the condition set section, it states that "grandfathering will apply if a step-preferred Prostate II drug is selected." Based on the 3 condition sets for Prostate II drugs, it seems possible that the Prostate II drugs may not require step therapy, thus access parity? If this occurs, I assume a PA will not be assigned to any of the Prostate II drugs? Same questions apply to the "UF VARR Appendix".

UFBPA chart

DoD P&T Class: ORAL ONCOLOGICAL AGENTS
 Class Note(s): The Prostate I drugs (first generation anti-androgens) are a subclass of the Oral Oncologic agents. A BCF drug may be selected from the Prostate I subclass.
 The Prostate II drugs (survival prolonging drugs for advanced prostate cancer) are a subclass of the Oral Oncologic agents. **Within the Prostate II subclass, there may be a step-preferred drug. Grandfathering will apply if a step preferred Prostate II drug is selected.**

PROSTATE II AGENTS				
Military Treatment Facility & Mail 152ONPCG1UFAS1X	Uniform Formulary & Tier 2 After Step Therapy	1	\$	\$
Military Treatment Facility & Mail 152ONPCG1UFBS1X	Uniform Formulary & Tier 2 Before Step Therapy	1	\$	\$
Military Treatment Facility & Mail 152ONPCG0UFNS1M	Uniform Formulary & Tier 2 No Step Therapy	1 or more	\$	\$

UF VARR Chart

DoD P&T Class: ORAL ONCOLOGICAL AGENTS
 Class Note(s): The Prostate I drugs (first generation anti-androgens) are a subclass of the Oral Oncologic agents.
 The Prostate II drugs (survival prolonging drugs for advanced prostate cancer) are a subclass of the Oral Oncologic agents. **Within the Prostate II subclass, there may be a step-preferred drug. Grandfathering will apply if a step preferred Prostate II drug is selected.**

PROSTATE II AGENTS							
152ONPCG1T2AS1X	Tier 2 After Step Therapy	1	\$	\$	%	%	%
152ONPCG1T2BS1X	Tier 2 Before Step Therapy	1	\$	\$	%	%	%
152ONPCG0T2NS1M	Tier 2 No Step Therapy	1 or more	\$	\$	%	%	%

A: Correct, if no step therapy is in place there will be access parity. PA criteria are currently in place for both Prostate II drugs, however the Committee may recommend otherwise during the meeting.

Q: Once the PEC P&T votes/approves its recommendations, what is the approx. date they will be available at the PEC/BAP website? When is the next BAP scheduled to take place in Washington, DC?

A: The BAP meeting following the February 2015 DoD P&T Committee meeting is currently scheduled for 26 March 2015. Information regarding the BAP meeting will be posted approximately 2 weeks in advance of the BAP meeting.

Post Teleconference Questions:

Q: I am aware Pfizer has a national contract in place for Viagra. I am aware that product is first in the step edit. In our quote/bid, can we offer a price if we choose to be first and preferred in the step edit or is that not even a possibility?

A: No. Quotes for conditions other than those solicited will be considered non-responsive. The bid will maintain a Tier 2 and after the step where a patient must try the BCF (Basic Core Formulary) preferred medication sildenafil. There are no condition sets for BCF placement as that entail a full class review.

Q: Xtandi® (enzalutamide) capsules is not available via retail pharmacies (is CVS, Walgreen's, Rite Aid, etc). Currently, it is available via Specialty Pharmacies and MTFs (UF BPA). Does VARR (and discount we will submit) apply to the "Specialty Pharmacy" channel?

A: In essence, yes, the VARR submission refers to the "specialty pharmacy" channel. However, we would prefer that you submit prices for each POS as indicated for the UF BPA and UF VARR. Currently, if an Xtandi Rx is sent to the Mail point of service it is filled in the Retail specialty pharmacy with Retail copays.

Q: I have another question related to the utilization provided for the Prostate II review. Are the units in "quantity dispensed" the total number of capsules/tablets dispensed each month? Appreciate your clarification on this.

A: On the historical factors tab the quantity dispensed refers to the dosage form in Column E.

***Anything said during this teleconference or listed on this document does not change what the solicitation states on the POD website. In case of inadvertent conflicts, the written solicitation governs.**