Clarifications and corrections to the June 27, 2005 Uniform Formulary Beneficiary Advisory Panel minutes

Clarifications to the Uniform Formulary Beneficiary Advisory Panel minutes are meant to provide the reader a more accurate description of DoD pharmacy policies, clinical and cost effectiveness analysis, and relevant clinical information. These clarifications highlight important concepts that lend transparency to the meeting minutes. The posted minutes reflect a detailed summary of the meeting.

Corrections to the Uniform Formulary Beneficiary Advisory Panel minutes are to correct errors in transcriptions so that the actual meeting proceedings are reflected accurately.

CLARIFICATIONS

1. Page 9, last paragraph: The answer given to Mr. Class's question referred to a shift to Levitra (the recommended UF PDE-5 Inhibitor) from Viagra and Cialis (PDE-5 Inhibitors recommended for non-formulary status on the UF).

2. Page 10, second paragraph: "Viagra was never added to the DoD Formulary as there was a policy letter signed by Dr. Sue Bailey at the time that would not allow PDE-5 Inhibitors to be on DoD formularies."

3. Page 11, second paragraph: add the following at the end of the paragraph: "certain triggers would be monitored (i.e. patent expirations, new landmark studies, etc.) that would trigger an expedited second review of a class already reviewed for UF."

4. Page 11, third paragraph: the last sentence should read "The mail order and retail points of service are not under the same budgetary system and are able to fill prescriptions at the $22 cost-share without having to file medical necessity in order to obtain the medication."

5. Page 12, third paragraph, last sentence: should have stated " Because of an administrative change, prior-authorizations for the PDE-5 class no longer expire (they used to last only for one year)." ."

6. Page 12, fourth paragraph change last sentence to read: "PDE-5 Inhibitors are only covered by TRICARE for organic causes of erectile dysfunction, psychological causes are not covered and that is the reason why a prior authorization is required for this class of drugs."

7. Page 13, third paragraph, first sentence: add "for Viagra or Cialis" after "necessity". Change the rest of the paragraph to read: "Individuals referred out to a network provider will have to establish medical necessity at the MTF to have the prescription filled at the MTF. This is assuming the MTF will fill prescriptions from individuals referred to a network provider. But the beneficiary has two other points of service he can use without having to establish medical necessity to receive the drug – the mail order or a network retail pharmacy, although the cost will be at the higher cost share ($22.00)"

8. Page 14, sixth paragraph: the following was read by CDR Graham: "from a report of PDE-5 Inhibitor Prior Authorization Review presented to the DoD P&T Committee presented by Mr. Dave Flowers in regards to frequency, approval rate, and sentinel effect.

Frequency: At TRRx and TMOP, there were approximately 680 requests for PDE-5 prior authorizations in the month of March 2005. This amount had been slightly increasing over the prior several months, gradually rising to this level from approximately 500 requests in the month of September 2004.

A significant reduction in the number of prior authorization requests occurred beginning in mid-August 2004. From June 2004 through August 2004, an average of over 3,000 requests occurred each month. The reduction beginning in August was attributed to the automatic granting of PDE-5 inhibitor coverage to all males age 50 or over. This change was effective in PDTS on 20 August 2004, and as a result, no males age 50 or over were required to follow the prior authorization process in order to obtain these products.

Approval Rate: Over the past ten months (June 2004 through March 2005), approximately 94% of all beneficiaries requesting prior authorization for PDE-5 inhibitors were granted approval. When the prior authorization requests were denied, there were three most commonly reported reasons. These reasons are presented below, in descending order of occurrence:

- PDE-5 is not being used for treatment of erectile dysfunction of organic origin
- PDE-5 is not being used for a male
- PDE-5 is not being used for the treatment of sexual dysfunction

Sentinel Effect: There are several measures that can be used to assess the impact of prior authorization criteria. Frequency of occurrence, approval rate, and examining denial reasons are all common measures that represent components of a good approach to assess how many beneficiaries initiated the prior authorization process, what was the eventual result, and why were these requests approved or denied.

An additional measure is assessing how many unique beneficiaries presented a prescription for a PDE-5 inhibitor in the TRRX and/or TMOP pharmacies, had this prescription rejected by PDTS at the point of service, and then chose not to initiate the formal prior authorization approval process by submitting either the required forms, or having their provider contract the prior authorization review team.

It was observed that for this class of medications, there were a very large number of beneficiaries that elected to not initiate the necessary formal steps to obtain prior authorization after receiving a rejection for a PDE-5 prescription at a TRRx or TMOP pharmacy.

The results for the first calendar quarter of 2005 (January through March 2005) are presented below:

- 5,176 = Beneficiaries with Unique Transaction Rejects in PDTS Requiring Prior Authorization
- 1,829 = Beneficiaries Entering the Prior Authorization Process
- 1,711 = Beneficiaries Awarded a Prior Authorization"

9. Page 14, seventh paragraph replace answer with: "A PDE-5 inhibitor may be rejected because of a drug interaction or because it requires a prior authorization. If the rejection is due to a drug interaction, the pharmacist may, using his clinical judgment, override this rejection and dispense the prescription. If the rejection is because a prior authorization is not already on file, a message will come back to the pharmacist stating, "requires prior authorization" and the prescription cannot be filled until the prior authorization is received."

CORRECTIONS

1. Page 6, last paragraph: "Data sources used for clinical evaluation include randomized clinical trials, published articles, identified through Medline and Cochrane databases; the VA PDE-5 drug class review, and manufacturer package inserts and dossiers. Additionally, manufacturers were invited to the PEC to present their most up-to-date clinical data."

2. Page 7, third paragraph: "Co-administration with nitrates is contraindicated with all PDE-5s. A labeling precaution regarding concomitant administration of the PDE-5s with alpha-blockers recommends starting at the lowest recommended PDE-5 dose. Vardenafil has demonstrated a slight increase in the QT interval therefore patients with congenital QT prolongation, and those taking Class IA or Class III antiarrhythmics medication, should avoid using vardenafil. The clinical significance of the QT changes is unknown. Vardenafil has a drug interaction warning associated with patients taking Class IA or Class III antiarrhythmics. The

most common side effects associated with PDE-5s are headache, flushing and dyspepsia. Sildenafil is associated with more visual side effects where tadalafil is associated with more back pain."

3. Page 11, fifth paragraph: change "angiotensin receptor blockers (ARB)" to "proton pump inhibitors (PPI)".

4. Page 18, last paragraph: change "15,000" to "13,000".

5. Page 19, last bullet: change to " · Cutaneous candidiasis (rash cause by yeast)".

6. Page 19, second paragraph: change to "Based on the relative clinical effectiveness, the P&T Committee concluded that the Uniform Formulary should include at least one agent from the azole/substituted pyridine sub-class; one agent from the allylamine sub-class; and Nystatin."

7. Page 19, first bullet: "For tinea pedis, the review found that allylamines were slightly more efficacious than the azoles, but that result depended on whether the article was published in English. Studies published in English showed slightly more efficacy for the allylamines; however, when non-English articles were evaluated (Spanish and German), there was no difference in efficacy between the allylamines and the azoles. Overall, the cure rates were similar (80% with allylamines vs. 73% with the azoles.) There was no difference in efficacy when individual azoles were compared with each other, or when individual allylamines were compared with each other. The efficacy of Ciclopirox was similar to the azoles. Nystatin is not effective for tinea pedis."

8. Page 20, second paragraph, last line: change "younger" to "pediatric".

9. Page 21, second from last paragraph: "Taking into consideration the conclusions from the relative clinical effectiveness and relative cost effectiveness determinations of the topical antifungals, the P&T Committee recommended that the status of econazole, sulconazole, ciclopirox, oxiconazole, and sertaconazole be changed from formulary to non-formulary, with butenafine, clotrimazole, ketoconazole, miconazole, naftifine, and nystatin maintaining formulary status with the formulary cost share."

10. Page 23, second paragraph from bottom, last sentence: add "ketaconazole" after "clotrimazole".