

June 16, 2005

Tricare Management Activity
Beneficiary Advisory Panel
c/o Mr. Richard Martel
5111 Leesburg Pike, Suite 810
Falls Church, VA 22041

Messrs. Chairman and Members of the Panel:

We are submitting this statement as an interested party with a unique composite of perspectives on the issue of Uniform Formulary (UF) determinations for the Phosphodiesterase 5 (PDE5) Inhibitor class. It is recognized that the stated purpose of the UF was to create a "uniform, consistent and equitable pharmacy benefit" that will provide adequate access to beneficiaries across the entire Military Health System. This objective is being challenged by the possibility that Viagra® (sildenafil citrate) will no longer be covered by the Department of Defense. This decision will have a significant impact on DoD beneficiaries currently treated for erectile dysfunction (ED) since the majority of these patients (>90%) receive Viagra®. In addition, this will likely result in significant administrative burden and potentially introduce unforeseeable costs to the entire TriCare Network.

There are important differences in the depth and breadth of clinical data favoring Viagra® as a preferred agent.¹ Over the past 10 years, the clinical efficacy and safety of Viagra® has been extensively researched in over 13,000 patients in more than 100 clinical trials. Viagra® has been studied in a broader patient population than any other PDE5 inhibitor, including those with cardiovascular disease, spinal cord injury, taking antidepressant and antihypertensive medications and following the treatment of prostate cancer. In evaluating the comparative efficacy of PDE5 agents, it is difficult to draw conclusions about similar effectiveness based on randomized placebo controlled trials since these studies were conducted in different patient populations and may have used different measures of effectiveness. For example, exclusion of prior PDE5 non-responders, as required in a number of competitor studies, would significantly increase the efficacy rates. In addition, contrary to the P&T Committee's conclusion, Padma-Nathan et al.² confirmed that ***head to head trials were conducted and submitted for Cialis^{®3,4} and Levitra^{®5} to the Food and Drug Administration and European Agency for Evaluation of Medicinal Products (EMA). These studies failed to demonstrate that Cialis[®] and Levitra[®] were not inferior to Viagra[®].***

The cardiovascular safety profile of Viagra® is well established. Neither Viagra® nor Cialis® have a precaution for QT prolongation or use with antiarrhythmic agents whereas Levitra® does. Additionally sildenafil citrate has shown

Cialis® is a registered trademark of Lillylcos. Viagra® is a registered trademark of Pfizer. Levitra® is a registered trademark of Bayer and GlaxoSmithKline. Revatio® is a registered trademark of Pfizer.

significant benefit in improving lung oxygenation and exercise tolerance in pulmonary arterial hypertension (PAH) patients and has recently been approved by the FDA as Revatio® for the treatment of PAH.

Limiting access to Viagra® may introduce additional costs to the DoD System associated with patients continuing utilization or switching back to Viagra® after trying a competitor. In a recent analysis of PDE5 inhibitor prescribing patterns using the NDCHealth's Intelligent Health Repository, only 6% of patients switched from Viagra® to a competitor and 22-27% switched back.⁶

In sum, we respectfully disagree with the P&T Committee's conclusions that the three PDE5 agents are comparable. The role of Viagra® as the preferred PDE5 agent for DoD beneficiaries is supported by existing head to head studies, a more established cardiovascular safety profile and the current dominant share of PDE5 prescriptions in the DoD. Left unchallenged, the P&T Committee's recommendations will place additional monetary and access burdens on the majority of DoD beneficiaries who are treated for ED and receive Viagra®. Thus, we are requesting that members of the BAP and Dr. Winkenwerder disagree with the P&T Committee's recommendations. Hopefully you will be successful in sending a positive message to Dr. Winkenwerder and the DoD P&T that preserving access to beneficial therapies is of critical importance. This was demonstrated in the March 2005 decision to maintain access to six of the seven angiotensin receptor blockers (ARBs) that were evaluated. We urge a similar consideration for Viagra® that will set the precedence for future medication class reviews.

Thank you for your consideration of this matter.

Sincerely,



Bob Sikora, RPh
Vice President - Clinical Education Consultants
Pfizer Global Pharmaceuticals
LTC, USA, MSC (Ret)



Evelyn L. Lewis, MD, MA
Director, Government Regional Medical Research Specialist
Pfizer Global Pharmaceuticals
CDR, MC, USN (Ret)

REFERENCES

¹ Anon. Vardenafil (Levitra) for Erectile Dysfunction The Medical Letter, Vol. 45, pg 77-78 September 29, 2003.

² Padma-Nathan H, McCullough A, Forest C. Erectile dysfunction secondary to nerve-sparing radical retropubic prostatectomy: comparative phosphodiesterase-5 inhibitor efficacy for therapy and novel prevention strategies. *Curr Urol Rep.* 2004 Dec;5(6):467-71.

³ European Agency for the Evaluation of Medicinal Products (EMA). Committee for Proprietary Medicinal Products European Public Assessment Report: Cialis—International Non-Proprietary Name: tadalafil (CPMP/3960/02). London: European Agency for the Evaluation of Medicinal Products, 2002. Available at: <http://www.emea.eu.int/humandocs/Humans/EPAR/cialis/cialis.htm>.
14. European Agency for the Evaluation of Medicinal Products (EMA). Committee for Proprietary

⁴ Cialis summary basis for approval. U.S. Food and Drug Administration. Available at: http://www.fda.gov/cder/foi/nda/2003/21-368_Cialis.htm.

⁵ European Agency for the Evaluation of Medicinal Products (EMA). Committee for Proprietary Medicinal Products European Public Assessment Report: Levitra—International Non-Proprietary Name: vardenafil (CPMP/6210/02). London: European Agency for the Evaluation of Medicinal Products, 2003. Available at: <http://www.emea.eu.int/humandocs/Humans/EPAR/levitra/levitra.htm>.

⁶ Harnett J, McLaughlin T, Burhani S, Scott B. Evaluation of tadalafil and vardenafil treatment patterns in prior sildenafil users. *Value in Health [abstract PIH17]* 2005; 8(3): 258