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On Drugs and Therapeutics

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IN BRIEF

Truvada for HIV Prevention

Truvada (Gilead), an oral fixed-dose combination of the antiretrovirals emtricitabine and tenofovir disoproxil fumarate frequently used for treatment of HIV infection,¹ has now also been approved by the FDA for pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 in adults at high risk. It is the first drug to be approved for this indication. The CDC has been recommending *Truvada* off-label for pre-exposure prophylaxis in men who have sex with men since 2011.² A 30-day supply of *Truvada* costs about \$1160.³

CLINICAL STUDIES — Approval for the new indication was based on 2 randomized, placebo-controlled trials in high-risk patients. One trial in 2,499 HIV-negative men (or transgender women) who have sex with men found that daily use of the combination reduced the risk of HIV seroconversion by 44% (36 seroconversions vs. 64 with placebo).⁴ A post-hoc analysis found that the rate of infection was reduced by 87.5% compared to placebo among men found to be adherent to the drug regimen (i.e., had detectable intracellular tenofovir levels).⁵ The second trial included 4,747 heterosexual couples among whom one partner was HIV-infected and the other was not. *Truvada* reduced the risk of becoming infected by 75% (13 seroconversions vs. 52 with placebo).⁶

RECOMMENDATIONS — Pre-exposure prophylaxis with *Truvada* should be considered only for persons who are at high risk for HIV-1 acquisition, are confirmed to be HIV-negative and are willing to take the drug once daily and practice safer sex. Frequent follow-up HIV antibody testing is recommended while taking the drug to ensure early diagnosis of newly-acquired HIV infection; resistance to tenofovir/emtricitabine can develop if it is taken prophylactically by patients with HIV infection.

1. Drugs for HIV infection. *Treat Guidel Med Lett* 2011; 9:29.
2. Centers for Disease Control and Prevention (CDC). Interim guidance: preexposure prophylaxis for the prevention of HIV infection in men who have sex with men. *MMWR Morb Mortal Wkly Rep* 2011; 60:65.
3. Wholesale acquisition cost (WAC). Source: PricePointRx™. Reprinted with permission by FDB. All rights reserved. ©2012. <http://www.firstdatabank.com/support/drug-pricing-policy.aspx>. Accessed July 25, 2012. Actual retail price may be higher.

4. RM Grant et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *N Engl J Med* 2010; 363:2587.
5. FDA. Background package for NDA 21-752/supplement 30. Available at: <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteeMeetingMaterials/Drugs/AntiviralDrugsAdvisoryCommittee/UCM303213.pdf>. Accessed July 25, 2012.
6. JM Baeten et al. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. *N Engl J Med* 2012 Jul 11 (epub).

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