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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.
