Truvada Approved for HIV Prophylaxis

On July 16, 2012 the FDA approved once daily Truvada (emtricitabine and tenofovir disoproxil fumarate) as the first drug for HIV pre-exposure prophylaxis (PrEP). Originally approved in 2004 for the treatment of HIV infection in people 12 years of age and older, this new indication for adults consists of the oral drug in combination with safer sex practices for PrEP to reduce the risk of sexually acquired HIV in adults who are considered high risk. For example, adults at high risk include those with partners known to be HIV infected. Other examples are people who are sexually active in areas with high prevalence of HIV as well as one of the following elements: inconsistent/no condom use, exchange of sex for commodities, use of illicit drugs, or partners of unknown HIV status with any of these listed factors. In conjunction with the new indication are Risk Evaluation and Mitigation Strategies (REMS). For instance, the prescribing physician must stress the importance of safe sex practices and also compliance with the once daily regimen to prevent acquisition of HIV infection, as well as screening at least every three months while taking Truvada to avoid development of resistant strains. Patients must also be confirmed HIV negative before starting PrEP therapy.

In 2008 there were an estimated 1,178,350 people age 13 and older living the United States with HIV. Moreover, estimates of HIV diagnosis in 2009 were 42,959 in 40 states and 5 United States dependent areas. There were two large, randomized, placebo-controlled, clinical trials conducted that looked at the safety and efficacy of Truvada for PrEP. In both trials the study populations were at high risk for HIV infection, but one study focused on men who have sex with men (iPrEx trial) and the other heterosexual serodiscordant couples (Partners PrEP trial). In these trials researchers found a reduction of the incidence of HIV acquisition in partners taking Truvada by 44% and 75%, respectively.

References:

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