Truvada® (emtricitabine/tenofovir disoproxil fumarate) – Expanded indication

- On May 15, 2018, the FDA announced the approval of Gilead's Truvada (emtricitabine [FTC]/tenofovir disoproxil fumarate [TDF]), in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually active human immunodeficiency virus type 1 (HIV-1) in at-risk adolescents weighing at least 35 kg.
    - Previously, Truvada was only approved for PrEP in adults at high risk.
    - Individuals must have a negative HIV-1 test immediately prior to initiating Truvada for HIV-1 PrEP.
- Truvada is also approved for use in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 17 kg.
- In the U.S., adolescents and young adults 13-24 years of age comprised 21% of all new HIV-1 infections in 2016, and 81% of the infections were among young men who have sex with men.
- The approval of Truvada's expanded indication is supported by data from well-controlled studies in adults, and additional data from safety and pharmacokinetic studies in previously conducted trials. The safety, adherence, and resistance were evaluated in a single-arm, open-label trial in 67 HIV-1 uninfected at-risk adolescent men who have sex with men. The safety of Truvada in this population was similar to that observed in the adult HIV-1 PrEP trials.
- Truvada carries a boxed warning regarding post-treatment acute exacerbation of hepatitis B and risk of drug resistance with use of Truvada for HIV-1 PrEP in undiagnosed early HIV-1 infection.
- In uninfected adults and adolescents weighing at least 35 kg, the recommended dosage of Truvada for HIV-1 PrEP is one tablet (containing 200 mg FTC and 300 mg TDF) orally once daily.
    - Refer to the Truvada drug label for additional dosage information, including for treatment of HIV-1 infection