Descovy® (emtricitabine/tenofovir alafenamide) – New indication

- On October 3, 2019, the FDA announced the approval of Gilead's Descovy (emtricitabine/tenofovir alafenamide), in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of human immunodeficiency virus-1 (HIV-1) infection from sexual acquisition, excluding individuals at risk from receptive vaginal sex.
    - Individuals must have a negative HIV-1 test immediately prior to initiating Descovy for HIV-1 PrEP.
    - The indication does not include use of Descovy in individuals at risk of HIV-1 from receptive vaginal sex because effectiveness in this population has not been evaluated.
- Descovy is also approved:
    - In combination with other antiretroviral agents, for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg
    - In combination with other antiretroviral agents other than protease inhibitors that require a CYP3A inhibitor, for the treatment of HIV-1 infection in pediatric patients weighing at least 25 kg and less than 35 kg.
- According to the Centers for Disease Control and Prevention, 38,739 people received an HIV diagnosis in the U.S. in 2017.
- PrEP is an HIV prevention method in which people who do not have HIV take medicine on a daily basis to reduce their risk of getting HIV if they are exposed to the virus.
    - Descovy for PrEP should be used as part of a comprehensive strategy, including adherence to daily administration and safer sex practices, including condoms, to reduce the risk of sexually acquired infections.
- The only other FDA-approved product for PrEP is Truvada® (emtricitabine/tenofovir disoproxil fumarate). Truvada is indicated in combination with safer sex practices for HIV-1 PrEP to reduce the risk of sexually acquired HIV-1 in at-risk adults and adolescents weighing at least 35 kg.
- The approval of Descovy for the new indication was based on DISCOVER, a randomized, double-blind study in HIV-seronegative men (N = 5,262) or transgender women (N = 73) who have sex with men and are at risk of HIV-1 infection. Patients received Descovy or Truvada. The primary outcome was the incidence of documented HIV-1 infection per 100 person-years in participants randomized to Descovy and Truvada (with a minimum follow-up of 48 weeks and at least 50% of participants having 96 weeks of follow-up).
    - Descovy was non-inferior to Truvada in reducing the risk of acquiring HIV-1 infection. The rate of HIV-1 infections per 100 person-years was 0.16 and 0.34 for Descovy and Truvada, respectively (rate ratio 0.468, 95% CI: 0.19, 1.15).
    - For both Descovy and Truvada, efficacy was strongly correlated to adherence to daily dosing.
- A boxed warning was added to the Descovy labeling for risk of drug resistance with use of Descovy for HIV-1 PrEP in undiagnosed early HIV-1 infection.
- Descovy also carries a boxed warning for post-treatment acute exacerbation of hepatitis B.

Continued . . .

- Descovy for HIV-1 PrEP is contraindicated in individuals with unknown or positive HIV-1 status.
- The most common adverse reaction (≥ 5%) with Descovy use in HIV-1 uninfected adults for PrEP was diarrhea.
- The recommended dose of Descovy for HIV-1 PrEP in uninfected adults and adolescents weighing at least 35 kg is one tablet (containing 200 mg of emtricitabine and 25 mg of tenofovir alafenamide) once daily taken orally with or without food.
    - All individuals should be screened for HIV-1 infection immediately prior to initiating Descovy for HIV-1 PrEP and at least once every 3 months while taking Descovy, and upon diagnosis of any other sexually transmitted infections.
    - If recent (< 1 month) exposures to HIV-1 are suspected or clinical symptoms consistent with acute HIV-1 infection are present, a test approved or cleared by the FDA should be used as an aid in the diagnosis of acute or primary HIV-1 infection.
    - Refer to the Descovy drug label for dosing for the treatment of HIV-1 infection and for other dosing and administration recommendations.