Descovy® (emtricitabine/tenofovir alafenamide) – Expanded indication

- On September 29, 2017, the FDA approved Gilead's Descovy (emtricitabine/tenofovir alafenamide) tablets, in combination with other antiretroviral agents, for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and pediatric patients weighting at least 35 kg; and 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 weighting at least 25 kg and less than 35 kg.
    - Previously, Descovy was indicated in combination with other antiretroviral agents, for the treatment of HIV-1 infection in adults and pediatric patients ≥ 12 years old.
    - Descovy is not indicated for use as pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 in adults at high risk.
- Descovy's expanded indication in pediatric patients is supported by an open-label trial in treatment-naïve HIV-1 pediatric patients (12 to < 18 years old, weighing ≥ 35 kg), an open-label trial in virologically-suppressed pediatric patients (6 to < 12 years old, weighing ≥ 25 kg), and by adequate and well-controlled studies in adults.
    - The safety and efficacy in these pediatric trials were similar to that of HIV-1 infected adults on a similar regimen (emtricitabine plus tenofovir alafenamide with elvitegravir plus cobicistat).
    - However, the safety and effectiveness of Descovy co-administered with an HIV-1 protease inhibitor that is administered with either ritonavir or cobicistat have not been established in pediatric subjects weighing < 35 kg.
    - The safety and effectiveness of Descovy in pediatric patients weighing < 25 kg have not been established.
- Descovy carries a boxed warning regarding post-treatment acute exacerbation of hepatitis B.
- In addition, the warning regarding bone loss and mineralization defects has been removed from the Descovy drug label.
- The recommended dosage of Descovy is 1 tablet orally once daily in adults and pediatric patients with body weight ≥ 25 kg and creatinine clearance (CrCl) ≥ 30 mL/min.
    - Prior to initiation of Descovy, patients should be tested for hepatitis B infection.
    - Estimated CrCl, urine glucose, and urine protein should be assessed before starting Descovy and should be monitored during therapy in all patients.

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