Biktarvy® (bictegravir/emtricitabine/tenofovir alafenamide) – Expanded indication, new strength

- On October 7, 2021, the FDA approved Gilead's Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide), as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and pediatric patients weighing ***at least 14 kg*** who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of Biktarvy.
    - Biktarvy was previously approved for this indication in adults and pediatric patients weighing ***at least 25 kg.***
- In addition to the expanded indication, the FDA also approved a new low dose strength of Biktarvy tablets (30 mg of bictegravir [BIC], 120 mg of emtricitabine [FTC], and 15 mg of tenofovir alafenamide [TAF]).
- The approval of Biktarvy for the expanded indication was based on a study of 22 virologically suppressed children at least 2 years of age and weighing at least 14 to less than 25 kg.
    - After switching to Biktarvy, 91% (20/22) of patients remained suppressed (HIV-1 RNA < 50 copies/mL) at week 24. HIV-1 RNA was not collected at week 24 for 2 patients because of COVID-19 pandemic-related study disruption.
- Biktarvy carries a boxed warning for post treatment acute exacerbation of hepatitis B.
- For pediatric patients weighing at least 14 kg to less than 25 kg, the recommended dosage of Biktarvy is one tablet containing 30 mg of BIC, 120 mg of FTC, and 15 mg of TAF taken orally once daily with or without food.
    - Refer to the Biktarvy drug label for dosing in adults and pediatric patients weighing at least 25 kg.
- Gilead's launch plans for the new low dosage strength of Biktarvy are pending.