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

- On June 19, 2019, 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 25 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 per mL) on a stable antiretroviral with no history of treatment failure and no known substitutions associated with resistance to the individual components of Biktarvy.
    - Previously, Biktarvy was only approved in adult patients.
- The approval of Biktarvy's expanded indication was based on an open-label, single-arm study in virologically suppressed HIV-1 infected patients between the ages of 12 to less than 18 years weighing at least 35 kg (cohort 1; n = 50) and patients between the ages of 6 to less than 12 years weighing at least 25 kg (cohort 2; n = 50).
    - After switching to Biktarvy, 98% (49/50) of patients in cohort 1 remained suppressed (HIV-1 RNA < 50 copies/mL) at week 48. The mean change from baseline in CD4+ cell count at week 48 was -22 cells/mm^3.
    - After switching to Biktarvy, 100% (50/50) of patients in cohort 2 remained suppressed (HIV-1 RNA < 50 copies/mL) at week 24. The mean change from baseline in CD4+ cell count at week 24 was -24 cells/mm^3.
- Biktarvy carries a boxed warning for post-treatment acute exacerbation of hepatitis B.
- The recommended dosage of Biktarvy is one tablet taken orally once daily with or without food in adults and pediatric patients weighing at least 25 kg.
- Each Biktarvy tablet contains 50 mg of bictegravir, 200 mg of emtricitabine, and 25 mg of tenofovir alafenamide.