Genvoya® (elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide) – Expanded indication

- On September 26, 2017, the FDA announced the approval of Gilead Sciences' Genvoya (elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide [TAF]) tablets, indicated as a complete regimen for the treatment of human immunodeficiency virus (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 < 50 copies/ mL) on a stable antiretroviral regimen for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Genvoya.
    - Previously, Genvoya was indicated in adults and pediatric patients 12 years of age and older weighing at least 35 kg.
- Genvoya is a four-drug combination of an HIV-1 integrase strand transfer inhibitor (elvitegravir); a CYP3A inhibitor (cobicistat); and two HIV-1 nucleoside analog reverse transcriptase inhibitors (emtricitabine and TAF).
- The approval of the expanded indication for Genvoya was based on an efficacy, safety, and pharmacokinetic open-label study in 23 virologically-suppressed children between the ages of 6 to less than 12 years weighing at least 25 kg.
    - After switching to Genvoya, 100% of patients remained suppressed (HIV-1 RNA < 50 copies/mL) at week 24.
    - All patients maintained CD4+ cell counts > 400 cells/mm^3.
- Genvoya carries a boxed warning for post treatment acute exacerbation of hepatitis B.
- The recommended dosage of Genvoya is one tablet taken orally once daily with food in adults and pediatric patients with a body weight of at least 25 kg.