Odefsey® (emtricitabine/rilpivirine/tenofovir alafenamide) – Expanded indication

- On February 19, 2025, the FDA approved Gilead's Odefsey (emtricitabine/rilpivirine/tenofovir alafenamide), as a complete regimen for the **treatment of HIV-1 infection in adult and pediatric patients weighing at least 25 kg**:
    - As initial therapy in those with no antiretroviral treatment history with HIV-1 RNA less than or equal to 100,000 copies/mL or
    - To replace a stable antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies/mL) for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Odefsey.
- Odefsey was previously approved for this indication in patients weighing at least 35 kg.
- Odefsey carries a boxed warning for post treatment acute exacerbation of hepatitis B.
- The recommended dosage of Odefsey is **one tablet taken orally once daily** with a meal in adults and pediatric patients with body weight at least 25 kg.
    - Odefsey is a three-drug fixed dose combination product containing 200 mg of emtricitabine, 25 mg of rilpivirine, and 25 mg of tenofovir alafenamide.