Atripla® (efavirenz/emtricitabine/tenofovir disoproxil fumarate) – Expanded indication and new contraindication

- On July 25, 2018, the FDA approved Gilead's Atripla (efavirenz/emtricitabine/ tenofovir disoproxil fumarate), as a complete regimen or in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and pediatric patients weighing at least 40 kg.
    - Previously, Atripla was only approved for adults and pediatric patients 12 years of age and older.
- Use of Atripla as a complete regimen for the treatment of HIV-1 infection in pediatric patients with body weight ≥ 40 kg is supported by adequate and well-controlled studies of Atripla in adults with HIV-1 infection and data from pediatric studies of the individual components of Atripla.
- Atripla carries a boxed warning for posttreatment acute exacerbation of hepatitis B.
- In addition, a new update has been added to the *Contraindications* section of the Atripla drug label indicating that Atripla is contraindicated for coadministration with Zepatier® (elbasvir/grazoprevir).
- In the *Warnings and Precautions* section of the Atripla drug label, a warning regarding coadministration with related products has been removed.
- The recommended dose of Atripla in adults and pediatric patients weighing at least 40 kg is one tablet once daily orally on an empty stomach. Dosing at bedtime may improve the tolerability of nervous system symptoms.
    - Prior to or when initiating Atripla, test patients for hepatitis B virus infection.
    - Prior to initiation and during use of Atripla, on a clinically appropriate schedule, assess serum creatinine, estimated creatinine clearance, urine glucose and urine protein in all patients. In patients with chronic kidney disease, also assess serum phosphorus.
    - Monitor hepatic function prior to and during treatment with Atripla.
    - Perform pregnancy testing before initiation of Atripla in adolescents and adults of childbearing potential.