November 6, 2015

**Genvoya Approved for HIV**

On Nov. 5, 2015, the U.S. Food and Drug Administration (FDA) approved Gilead’s combination drug, Genvoya® (elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide). It was approved for the once-daily treatment of patients who are age 12 years and older, who weigh at least 35kg (about 77 pounds) and who have HIV-1. Both patients who have not yet been treated and patients who have had suppressed viral loads for at least six months on a previous HIV drug regimen will be able to use it. However, eligible patients must not have failed prior treatment or developed resistance to any of the components of Genvoya. In addition to three drugs already approved for treating HIV, Genvoya includes a new nucleotide reverse transcriptase inhibitor (NRTI), tenofovir alafenamide (TAF). While it is similar to Viread® (tenofovir disoproxil – Gilead), TAF is effective in much smaller doses, so it has less risk of causing kidney damage and bone mineral density problems than tenofovir disoproxil.

Shipments of the drug are expected to begin next week. Complete prescribing information for Genvoya is at: [www.genvoya.com](http://www.genvoya.com)

► **At a Glance**

- **Brand (Generic) Drug:** Genvoya® (elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide)
- **Manufacturer:** Gilead Sciences, Inc.
- **Date Approved:** Nov. 5, 2015
- **Indications:** For treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older who have no antiretroviral treatment history or for replacement of the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies per 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
- **Dosage Forms Available:** Once-daily oral tablets each containing 150mg of elvitegravir, 150mg of cobicistat, 200mg of emtricitabine and 10mg of tenofovir alafenamide
- **Specialty Status:** It will be added to Express Scripts’ specialty drug lists that include oral HIV medications.
- Genvoya is the first approved drug containing tenofovir alafenamide (TAF), which is effective at lower doses than tenofovir disoproxil (TDF). Its other components -- elvitegravir, cobicistat and emtricitabine -- are the same as in Gilead’s Stribild®
- Labeling for Genvoya has a boxed warning that it may cause potentially deadly liver problems or lactic acid accumulation.
- Because emtricitabine and tenofovir disoproxil have reactivated cases of hepatitis B, Genvoya should not be used to treat patients who have hepatitis B.
- Two other combination products that contain TAF are being reviewed by FDA with action dates in the first half of 2016.
- The patent on Gilead’s Viread is set to expire in Jan 2018. The approval of the new formulations will allow Gilead to convert market share to the new TAF-containing products in advance of potential generic competition.