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Gilead’s Biktarvy gets FDA nod to treat HIV-1 Infection

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Biktarvy (bictegravir, emtricitabine, tenofovir alafenamide) is indicated as a complete regimen for the treatment of HIV-1 infection in adults who have no antiretroviral treatment history

Gilead Sciences, Inc. announced that the U.S. Food and Drug Administration (FDA) has approved Biktarvy a once-daily single tablet regimen (STR) for the treatment of HIV-1 infection.

Biktarvy combines the novel, unboosted integrase strand transfer inhibitor (INSTI) bictegravir, with the demonstrated safety and efficacy profile of the Descovy (FTC/TAF) dual nucleoside reverse transcriptase inhibitor (NRTI) backbone, and is the smallest INSTI-based triple-therapy STR available.

Biktarvy is indicated as a complete regimen for the treatment of HIV-1 infection in adults who have no antiretroviral treatment history.

It is also specified to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA <50 c/mL) on a stable antiretroviral regimen for at least three months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Biktarvy.

No dosage adjustment of Biktarvy is required in patients with estimated creatinine clearance greater than or equal to 30 mL per minute.

Biktarvy does not require testing for HLA-B*5701, has no food intake requirements, and has no baseline viral load or CD4 count restrictions.

Prior to treatment with Biktarvy, It’s suggested to test for renal function and hepatitis B virus (HBV) infection.