

## Vemlidy® (tenofovir alafenamide) – Expanded indication

- On October 17, 2022, the <u>FDA approved</u> Gilead's <u>Vemlidy (tenofovir alafenamide)</u>, for the treatment of chronic hepatitis B virus (HBV) infection in adults and pediatric patients 12 years of age and older with compensated liver disease.
  - Vemlidy was previously approved for this indication in adults only.
- The approval of Vemlidy for the expanded indication was based on Trial 1092, a randomized, double-blind, placebo-controlled study in 70 treatment-naïve and treatment-experienced chronic HBV-infected patients between the ages of 12 to less than 18 years. Patients were randomized to receive Vemlidy or placebo.
  - Overall, 21% (10/47) of patients treated with Vemlidy achieved HBV DNA < 20 IU/mL at week 24 vs. 0% (0/23) of patients treated with placebo.
  - At week 24, the overall mean change from baseline in HBV DNA for Vemlidy and placebo groups, respectively, was -5.04 log<sub>10</sub> IU/mL and -0.13 log<sub>10</sub> IU/mL.
- Vemlidy carries a boxed warning for post-treatment severe acute exacerbation of hepatitis B.
- The recommended dosage of Vemlidy in adults and pediatric patients 12 years of age and older is one 25 mg tablet taken orally once daily with food.



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