

SUPPLEMENTAL SPECIALTY PA

VEMLIDY (tenofovir alafenamide)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication

Vemlidy is indicated for the treatment of chronic hepatitis B virus (HBV) infection in adults and pediatric patients 6 years of age and older and weighing at least 25 kg with compensated liver disease.

B. Compendial Use

1. Coinfection with chronic hepatitis B virus and human immunodeficiency virus (HIV)
2. Hepatitis B virus reactivation/reinfection prophylaxis

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. **Chronic hepatitis B virus infection and coinfection with chronic hepatitis B virus and HIV**

Authorization of 6 months may be granted for treatment of chronic hepatitis B virus (HBV) when both of the following criteria are met:

1. Member has compensated liver disease as evidenced by all of the following criteria:
 - i. No evidence of ascites, hepatic encephalopathy, or variceal bleeding.
 - ii. International normalized ratio (INR) less than 1.5 times upper limit of normal (ULN).
 - iii. Total bilirubin less than 2.5 times ULN.
 - iv. Albumin greater than 3.0 g/dL.
2. Member meets either of the following criteria:
 - i. Member is HIV-1 negative.
 - ii. Member has coinfection with chronic hepatitis B and HIV and is currently receiving antiretroviral therapy regimen consists of emtricitabine or lamivudine.

B. **Hepatitis B virus reactivation/reinfection prophylaxis**

Authorization of 12 months may be granted for prophylaxis of hepatitis B virus reactivation/reinfection in immunosuppressed members.

III. CONTINUATION OF THERAPY

A. **Chronic hepatitis B virus infection and coinfection with chronic hepatitis B and HIV**

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for chronic HBV infection or coinfection with chronic HBV and HIV who achieve or maintain positive clinical response (e.g., decreased HBV DNA level, ALT normalization, HBsAg and/or HBeAg loss and seroconversion).

B. Hepatitis B virus reactivation/reinfection prophylaxis

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Vemlidy [package insert]. Foster City, CA: Gilead Sciences, Inc.; March 2024.
2. The U.S. Department of Health and Human Services (HHS) Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in adults and adolescents with HIV. Department of Health and Human Services. Available at <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf>. Accessed March 11, 2024.
3. Terrault NA, Lok ASF, McMahon BJ, et al. Update on prevention, diagnosis, and treatment of chronic hepatitis B: AASLD 2018 hepatitis B guidance. *Hepatology*. 2018;67(4):1560-1599.
4. Micromedex® (electronic version). Merative, Ann Arbor, MI. Available at: <http://micromedexsolutions.com/>. (cited: March 5, 2024).
5. Clinical Pharmacology [Internet]. Tampa (FL): Elsevier; 2024 [cited 2024 Mar 5]. Available from: <http://www.clinicalpharmacology.com>.
6. Lexicomp Online, Pediatric and Neonatal Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed March 5, 2024.