

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 12 years of age and older with compensated liver disease.

B. Compendial Use

1. Coinfection with chronic hepatitis B virus and 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**

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

1. Member is HIV-1 negative
2. Member has compensated liver disease as evidenced by:
 - i. No evidence of ascites, hepatic encephalopathy, or variceal bleeding
 - ii. International normalized ratio (INR) less than 1.5x upper limit of normal (ULN)
 - iii. Total bilirubin less than 2.5x ULN
 - iv. Albumin greater than 3.0 g/dL

B. **Coinfection with chronic hepatitis B virus and HIV**

Authorization of 6 months may be granted for treatment of coinfection with chronic hepatitis B virus and HIV when all of the following criteria are met:

1. Vemlidy will not be used as monotherapy for treatment of chronic hepatitis B virus and HIV coinfection
2. Member's antiretroviral therapy regimen consists of either emtricitabine or lamivudine
3. Member has compensated liver disease as evidenced by:
 - i. No evidence of ascites, hepatic encephalopathy, or variceal bleeding
 - ii. International normalized ratio (INR) less than 1.5x upper limit of normal (ULN)
 - iii. Total bilirubin less than 2.5x ULN
 - iv. Albumin greater than 3.0 g/dL

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

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

Reference number(s)
2901-A

III. CONTINUATION OF THERAPY

A. Chronic hepatitis B virus infection

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for chronic HBV who achieve or maintain positive clinical response (e.g., decreased HBV DNA level, ALT normalization, HBsAg and/or HBeAg loss and seroconversion) and are HIV-1 negative.

B. Coinfection with chronic hepatitis B virus and HIV

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for 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).

C. 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.; October 2022.
2. 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 1, 2023.
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. doi: 10.1002/hep.29800.
4. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. <http://micromedex.com/>. Accessed March 1, 2023.
5. Clinical Pharmacology [Internet]. Tampa (FL): Elsevier; 2023 [cited 2023 Mar 1]. Available from: <http://www.clinicalpharmacology.com>.
6. Lexicomp Online, Pediatric and Neonatal Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2023. <https://online.lexi.com>. Accessed March 1, 2023.