



## Commercial/Healthcare Exchange PA Criteria Effective: January 1, 2021

**Prior Authorization:** Vemlidy (tenofovir alafenamide fumarate)

**Products Affected:** Vemlidy oral tablet

**Medication Description:**

Tenofovir alafenamide is indicated for the treatment of chronic hepatitis B virus (HBV) infection in adults with compensated liver disease. Tenofovir alafenamide is a prodrug converted to tenofovir, and then into tenofovir diphosphate which inhibits replication of hepatitis B virus by incorporating into the viral DNA, thus resulting in DNA chain termination. Hepatitis B is a virus that infects the liver, spread through contact with the blood and body fluids of an infected person. Chronic hepatitis B virus (HBV) infection occurs in approximately 5% to 10% of individuals with acute HBV infection. HBV infection is a global public health problem, and in the United States, the National Health and Nutrition Examination Survey (1999 to 2008) identified approximately 704,000 adults with chronic hepatitis B (CHB), but with adjustments for hepatitis B infection among foreign-born persons, the upper estimate of CHB in the United States may be as high as 2.2 million. The goals of antiviral treatment are to decrease the morbidity and mortality related to CHB. The achievement of a sustained suppression of HBV replication has been associated with normalization of serum ALT, loss of HBeAg with or without detection of antibodies to HBeAg, and improvement in liver histology

**Covered Uses:** Treatment of chronic hepatitis B virus (HBV) infection in adults with compensated liver disease.

**Exclusion Criteria:**

1. Non FDA approved indication(s)
2. Patients with underlying renal dysfunction (chronic administration of Vemlidy may result in nephrotoxicity)

**Required Medical Information:**

1. Diagnosis
2. Documentation of Active Hepatitis B (HBV DNA viral load)
3. Previous treatment history
4. Liver Function tests

**Age Restrictions:** 18 years or older

**Prescriber Restrictions:** Prescribed by or in consultation with a Gastroenterologist, Hepatologist, or Infectious Disease Specialist

**Coverage Duration:** 12 months

January 2021

**Other Criteria:**

**Initiation**

Approve Vemlidy if the patient meets the following criteria:

- A. Patient has diagnosis of Chronic Hepatitis B (HBsAg positive or negative for at least 6 months); **AND**
- B. There is documented evidence of active viral replication (HBeAG+ and HBV DNA > 100,000 copies/mL); **AND**
- C. There is documented evidence of active liver disease as demonstrated by persistent elevation in serum ALT (greater than 2 times normal) or moderate to severe hepatitis on biopsy; **AND**
- D. The patient had a trial and failure of Viread or Baraclude/entecavir; **OR**
- E. The patient has documented resistance to Viread and/or entecavir (Baraclude)

**Continuation**

For reauthorization, the patient must have a documented diagnosis of chronic hepatitis b virus (HBV) infection, AND meet the criteria specified below:

- A. Patient has compensated liver disease (no evidence of ascites, hepatic encephalopathy, variceal bleeding, INR <1.5× ULN, total bilirubin <2.5× ULN, and albumin >3.0 g/dL), **AND**
- B. Patient has been tested for and remains HIV-1 negative, **AND**
- C. Prescriber is attesting that patient is responding positively to therapy.

**References:**

1. Vemlidy (tenofovir alafenamide) [prescribing information]. Foster City, CA: Gilead Sciences; November 2016.
2. Terrault, N. A., Bzowej, N. H., Chang, K.-M., et al. AASLD guidelines for treatment of chronic hepatitis B. *Hepatology*, 63: 261–283. doi:10.1002/hep.28156. Available at: [http://www.aasld.org/sites/default/files/guideline\\_documents/hep28156.pdf](http://www.aasld.org/sites/default/files/guideline_documents/hep28156.pdf). Accessed December 20, 2016
3. Centers for Disease Control and Prevention (CDC) Division of Viral Hepatitis. Hepatitis B FAQs for Health Professionals (2016). Available at: <http://www.cdc.gov/hepatitis/HBV/HBVfaq.htm>. Accessed December 20, 2016.
4. Angus PW, Patterson SJ, Strasser SI, et al: A randomized study of adefovir dipivoxil in place of HBIG in combination with lamivudine as post-liver transplantation hepatitis B prophylaxis. *Hepatology* 2008; 48(5):1460-1466.  
PubMed Abstract: <http://www.ncbi.nlm.nih.gov/...>
5. Lo CM, Liu CL, Lau GK, et al: Liver transplantation for chronic hepatitis B with lamivudine-resistant YMDD mutant using add-on adefovir dipivoxil plus lamivudine. *Liver Transpl* 2005; 11(7):807-813.  
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6. Lacombe K, Gozlan J, Boyd A, et al: Comparison of the antiviral activity of adefovir and tenofovir on hepatitis B virus in HIV-HBV-coinfected patients. *Antivir.Ther* 2008; 13(5):705-713.  
PubMed Abstract: <http://www.ncbi.nlm.nih.gov/...>
7. AIDSinfo: Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. AIDSinfo. Rockville, MD. 2015. Available from URL: <http://aidsinfo.n...> . As accessed 2016-05-03.

**Policy Revision history**

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	1/1/2021