Generic Name: Tenofovir Alafenamide

Applicable Drugs: Vemlidy

Preferred: Entecavir (generic), Tenofovir Disoproxil Fumarate (generic)

Non-preferred: Vemlidy

Date of Origin: 7/31/2018

Date Last Reviewed / Revised: 10/27/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through VI are met)

I. Documented diagnosis of one of the following conditions (A through F) and must meet ALL applicable criteria:

A. Treatment of chronic hepatitis B (CHB)

i. Refer to Appendix Table 1 for criteria by population.

B. Treatment of Hepatitis B during pregnancy (not meeting criteria A) to prevent mother-to-child transmission with documentation of i and ii.

i. HBsAg positive.

ii. HBV-DNA level > 200,000 IU/mL.

C. Post-liver transplantation and documentation of i or ii.

i. HBsAg-negative liver transplant recipient who received a HBsAg-negative, antibody to hepatitis B core antigen (anti-HBc)-positive graft.

ii. HBsAg-positive liver transplant recipient with documented chronic hepatitis B infection prior to transplant.

D. Treatment of patient with prior history of hepatitis B infection who is undergoing immunosuppression related to non-liver solid organ transplantation.

E. Prophylactic HBV treatment in patients with a prior history of Hepatitis B receiving immunosuppressive or cytotoxic therapy within the past 12 months with documentation of i or ii:

i. HBsAg-positive and anti-HBc-positive.

ii. HBsAg-negative and anti-HBc-positive (receiving anti-CD20 antibody therapy [eg. rituximab] or undergoing stem cell transplantation only).

II. Age ≥ 6 years old and weight ≥ 25 kg.

III. Documentation of treatment failure or contraindication to entecavir or tenofovir disoproxil fumarate.

IV. Treatment must be prescribed by or in consultation with a gastroenterologist, infectious disease specialist, or hepatologist.

V. Medication is prescribed in accordance with FDA labeling or current clinical practice guidelines.

VI. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Decompensated (Child-Pugh B or C) hepatic impairment.
- Estimated creatinine clearance < 15mL/min, unless patient is receiving chronic dialysis.

OTHER CRITERIA

- Recent (within last 7 days) documented negative HIV-1/2 antigen/antibody test, unless being prescribed in combination with other antivirals as part of an HIV co-infection treatment regimen with 2 drugs having activity against HBV.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 30 tablets per 30 days

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** 1 year, with progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

Table 1. Chronic Hepatitis B (CHB) Criteria and Treatment Recommendations[2]

Population	CHB Criteria	Treatment Duration Recommendations
Adults (≥ 18 years old)	Documentation of <u>all</u> the following criteria (1 through 3): 1. HBsAg positive for ≥ 6 months. 2. Baseline HBV-DNA level. 3. Genotypic viral testing showing sensitivity and treatment history (only required for treatment-experienced patients). (continued on next page)	HBeAg positive with seroconversion to anti-HBe on NA therapy: minimum of 12 additional months[c] HBeAg negative: indefinite[d] Persistent low-level viremia[e]: continue regardless of ALT Virological breakthrough[f] on NA monotherapy[g]: refer to Table 2.

Population	CHB Criteria	Treatment Duration Recommendations
	There must also be documentation of at least one of the following criteria (4 through 6): 4. Evidence of significant histologic disease[a] by fibrosis assessment testing[b] 5. ALT >2 times the ULN[c] AND HBV-DNA >2,000 IU/mL (HBeAg negative) or >20,000 IU/mL (HBeAg positive) 6. ALT < 2 times the ULN AND HBV DNA ≤2,000 IU/mL (HBeAg negative) or ≤20,000 IU/mL (HBeAg positive) with ONE of the following risk factors: i. Age > 40 years old ii. Family history of cirrhosis or hepatocellular carcinoma iii. Previous treatment history iv. Presence of extrahepatic manifestations	
Children (6 to 18 years old)	Documentation of all the following criteria (1 through 4): 1. HBsAg positive for ≥ 6 months 2. HBeAg positive 3. ALT > 1.3 times the ULN[c] for at least 6 months 4. Measurable HBV-DNA levels.	HBeAg positive who seroconvert to anti-HBe on NA therapy: continue an additional 12 months

[a] Moderate-to-severe inflammation (A2 or A3) and/or significant fibrosis (≥F2). [b]Such as liver biopsy, FIB-4, FibroScan, Fibrotest, or Fibrosure. [c]The upper limit of normal for ALT is defined as 35 U/L for males and 25 U/L females. [d]unless strong competing rationale for treatment discontinuation. [e]< 2,000 IU/mL. [f]Defined as a serum HBV-DNA level ≥ 100 IU/mL after achieving a previously undetectable level (<10 IU/mL) in a patient adherent with therapy. [g]tenofovir or entecavir.
Abbreviations: ALT, alanine aminotransferase; CHB, chronic hepatitis B; HBeAg, hepatitis B e antigen; HBsAg, hepatitis B surface antigen; NA, nucleos(t)ide analogue; ULN, upper limits of normal.

Table 2. Management of Nucleos(t)ide Analogue (NA) Antiviral Resistance[2]

Antiviral Resistance to Drug[a]	Monotherapy[b]	Dual antiviral therapy[c]
Adefovir	Entecavir, TDF, or TAF	Adefovir and entecavir
Entecavir	TDF or TAF	Entecavir and TDF or TAF OR 3TC/ TDF or TAF
Lamivudine	TDF or TAF	Lamivudine and TDF or TAF OR 3TC/ TDF or TAF
Telbivudine	TDF or TAF	Telbivudine and TDF or TAF
Tenofovir (TDF or TAF)	Entecavir	TDF or TAF and entecavir
Multidrug	TDF or TAF	TDF or TAF and entecavir

[a]Verified by genotypic testing; [b] Switching to monotherapy with a NA with a high barrier to resistance is the preferred strategy [c]When preferred therapy cannot be used, adding on another drug without cross-resistance is an alternative.
Abbreviations: 3TC, emtricitabine; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate.

REFERENCES

1. Vemlidy. Prescribing information. Gilead Sciences, Inc; 2024. Accessed October 27, 2025. https://www.gilead.com/~/media/files/pdfs/medicines/liver-disease/vemlidy/vemlidy_pi.pdf?la=en
2. 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

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.