

Latest treatment guidelines and algorithms are

EXPANDING TREATMENT CRITERIA¹⁻³

Consider earlier treatment for chronic hepatitis B in adults with compensated liver disease

VEMLIDY is a preferred **first-line therapy** for patients with chronic hepatitis B as recommended by AASLD and SABA^{1,3,a}

AASLD=American Association for the Study of Liver Diseases; SABA=Simplified Approach Hepatitis B Algorithm.

^aOther recommended first-line nucleoside/nucleotide analogs are entecavir and tenofovir disoproxil fumarate.^{1,3}

INDICATION

VEMLIDY is indicated for the treatment of chronic hepatitis B virus (HBV) infection in adults with compensated liver disease.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: POSTTREATMENT SEVERE ACUTE EXACERBATION OF HEPATITIS B

- Discontinuation of anti-hepatitis B therapy, including VEMLIDY, may result in severe acute exacerbations of hepatitis B. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who discontinue anti-hepatitis B therapy, including VEMLIDY. If appropriate, resumption of anti-hepatitis B therapy may be warranted.

Warnings and Precautions

- **Risk of Development of HIV-1 Resistance in HBV/HIV-1 Coinfected Patients:** Due to this risk, VEMLIDY alone should not be used for the treatment of HIV-1 infection. Safety and efficacy of VEMLIDY have not been established in HBV/HIV-1 coinfecting patients. HIV antibody testing should be offered to all HBV-infected patients before initiating therapy with VEMLIDY, and, if positive, an appropriate antiretroviral combination regimen that is recommended for HBV/HIV-1 coinfecting patients should be used.

Click here for full Prescribing Information for VEMLIDY, including **BOXED WARNING** on posttreatment severe acute exacerbation of hepatitis B.

 **Vemlidy**[®]
tenofovir alafenamide 25mg tablets

The latest 2025 American Association for the Study of Liver Diseases (AASLD) guidelines expand the types of patients with chronic hepatitis B who should be considered for treatment^{1,2}

■ Indicates 2025 expanded treatment recommendations

	HBeAg+		
	ALT ^a	HBV DNA $\geq 20,000^b$ to < 10 million IU/mL	HBV DNA > 10 million IU/mL
HBsAg+	\leq ULN	Monitor Consider treatment based on shared decision-making	Monitor Consider treatment if: • age ≥ 40 years, significant inflammation ($\geq A2$), or fibrosis ($\geq F2$) • age < 40 years, based on shared decision-making
	$1\times - < 2\times$ ULN	Monitor Consider treatment based on shared decision-making	
	$\geq 2\times$ ULN	Treat	

	HBeAg-		
	ALT ^a	HBV DNA < 2000 IU/mL	HBV DNA ≥ 2000 IU/mL
HBsAg+	\leq ULN	Monitor	Consider treatment based on shared decision-making ^{c,d}
	$1\times - < 2\times$ ULN	Monitor ^e Consider treatment based on shared decision-making ^d	Treat
	$\geq 2\times$ ULN		

HBsAg+

HBeAg-



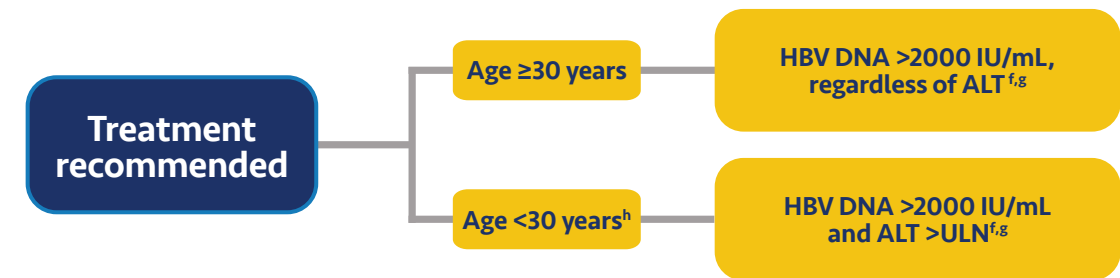
Shared decision-making approach

A collaborative process where a healthcare provider and patient make informed healthcare decisions by considering clinical evidence, taking into account the individual's personal values, preferences, and circumstances, allowing the patient to actively participate in choosing the best treatment option for them¹

ALT=alanine aminotransferase; HBeAg=hepatitis B envelope antigen; HBsAg=hepatitis B surface antigen; HBV=hepatitis B virus; ULN=upper limit of normal.
^aAASLD 2025 ULN criteria: 35 U/L for men and 25 U/L for women.¹
^bIndividuals who are HBeAg-positive with HBV DNA $< 20,000$ IU/mL are extremely rare, but the treatment approach would be the same as those with HBV DNA $\geq 20,000$ IU/mL.¹
^cBased on risk factors such as male sex, age > 40 , and platelet count $< 180,000/\text{mm}^3$.¹
^dPatients with advanced fibrosis ($\geq F3$) should receive treatment.¹
^eEvaluate for other causes of ALT elevation.¹

Consider the Simplified Approach Hepatitis B Algorithm (SABA) to initiate earlier treatment for appropriate patients with chronic hepatitis B³

In patients with chronic hepatitis B, SABA 2022 recommends treatment for those with compensated liver disease and detectable HBV DNA, regardless of ALT levels or HBeAg status.³



- Refer to a specialist if HIV coinfection exists
- VEMLIDY is not indicated for patients with decompensated (Child-Pugh B or C) hepatic impairment and has not been tested in this population⁴



VEMLIDY is a **recommended FIRST-LINE therapy** for patients with chronic hepatitis B^{3,i}
 VEMLIDY **can be considered** in patients with, or at risk for, renal dysfunction and bone disease^{3,j}

^fSABA 2022 ULN criteria: 30 U/L for men and 19 U/L for women.³

^gIf HBV DNA < 2000 IU/mL OR if age < 30 years and HBV DNA > 2000 IU/mL and ALT \leq ULN, then re-evaluate for treatment eligibility in 6 months. Assess ALT and HBV DNA every 6 months for 2 years, then annually if no change; assess HBsAg every 2 years.³

^hVEMLIDY is indicated for the treatment of chronic HBV infection in adults with compensated liver disease.⁴

ⁱOther recommended first-line nucleoside/nucleotide analogs are entecavir and tenofovir disoproxil fumarate.¹

^jVEMLIDY is not recommended in patients with end-stage renal disease (ESRD; eCrCl=estimated creatinine clearance < 15 mL/min) who are not receiving chronic hemodialysis; in patients on chronic hemodialysis, on hemodialysis days, administer VEMLIDY after completion of hemodialysis treatment.⁴

IMPORTANT SAFETY INFORMATION (cont.)

Warnings and Precautions (cont.)

- **New Onset or Worsening Renal Impairment:** Postmarketing cases of renal impairment, including acute renal failure, proximal renal tubulopathy (PRT), and Fanconi syndrome have been reported with TAF-containing products. Patients with impaired renal function and/or taking nephrotoxic agents (including NSAIDs) are at increased risk of renal-related adverse reactions. Discontinue VEMLIDY in patients who develop clinically significant decreases in renal function or evidence of Fanconi syndrome. Monitor renal function in all patients – See Dosage and Administration.
- **Lactic Acidosis and Severe Hepatomegaly with Steatosis:** Fatal cases have been reported with the use of nucleoside analogs, including tenofovir disoproxil fumarate (TDF). Discontinue VEMLIDY if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations.

Adverse Reactions

Most common adverse reactions (incidence $\geq 5\%$; all grades) in clinical studies through week 144 were headache, upper respiratory tract infection, abdominal pain, cough, back pain, arthralgia, fatigue, nausea, diarrhea, dyspepsia, and pyrexia.

Click here for full Prescribing Information for VEMLIDY, including **BOXED WARNING** on posttreatment severe acute exacerbation of hepatitis B.



Could earlier intervention benefit your chronic hepatitis B patients with compensated liver disease?

Consider VEMLIDY, a preferred *first-line treatment* as recommended by AASLD and SABA^{1,3,a}

^aOther recommended first-line nucleoside/nucleotide analogs are entecavir and tenofovir disoproxil fumarate.^{1,3}

INDICATION

VEMLIDY is indicated for the treatment of chronic hepatitis B virus (HBV) infection in adults with compensated liver disease.

IMPORTANT SAFETY INFORMATION (cont.)

Drug Interactions

- Coadministration of VEMLIDY with drugs that reduce renal function or compete for active tubular secretion may increase concentrations of tenofovir and the risk of adverse reactions.
- Coadministration of VEMLIDY is not recommended with the following: oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine, or St. John's wort. Such coadministration is expected to decrease the concentration of tenofovir alafenamide, reducing the therapeutic effect of VEMLIDY. Drugs that strongly affect P-glycoprotein (P-gp) and breast cancer resistance protein (BCRP) activity may lead to changes in VEMLIDY absorption.

Consult the full prescribing information for VEMLIDY for more information on potentially significant drug interactions, including clinical comments.

Dosage and Administration

- **Testing Prior to Initiation:** HIV infection.
- **Prior to or When Initiating, and During Treatment:** On a clinically appropriate schedule, assess serum creatinine, estimated creatinine clearance, urine glucose, and urine protein in all patients. In patients with chronic kidney disease, also assess serum phosphorus.
- **Dosage in Adults:** 1 tablet taken once daily with food.
- **Renal Impairment:** Not recommended in patients with end stage renal disease (ESRD; eCrCl <15 mL/min) who are not receiving chronic hemodialysis; in patients on chronic hemodialysis, on hemodialysis days, administer VEMLIDY after completion of hemodialysis treatment.
- **Hepatic Impairment:** Not recommended in patients with decompensated (Child-Pugh B or C) hepatic impairment.

Pregnancy and Lactation

- **Pregnancy:** A pregnancy registry has been established for VEMLIDY. Available clinical trial data show no significant difference in the overall risk of birth defects for VEMLIDY compared with the background rate of major birth defects in the U.S. reference population.
- **Lactation:** TAF and tenofovir can pass into breast milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VEMLIDY and any potential adverse effects on the breastfed infant from VEMLIDY or from the underlying maternal condition.

[Click here for full Prescribing Information for VEMLIDY, including **BOXED WARNING** on posttreatment severe acute exacerbation of hepatitis B.](#)

References: **1.** Ghany MG, Pan CQ, Lok AS, et al. AASLD IDSA Practice Guideline on treatment of chronic hepatitis B. *Hepatology*. 2026;83(4):974-997. doi:10.1097/HEP.0000000000001549 **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 **3.** Dieterich D, Graham C, Wang S, et al. It is time for a simplified approach to hepatitis B elimination. *Gastro Hep Adv*. 2022;2(2):209-218. doi:10.1016/j.gastha.2022.10.004 **4.** VEMLIDY Prescribing Information. Foster City, CA: Gilead Sciences, Inc.; March 2024.

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