For the moments that matter

Choose VEMLIDY
Pivotal and long-term data results[1-6]

SEE PIVOTAL AND 8-YEAR DATA INSIDE

Actor portrayals.

Explore long-term VEMLIDY data for your appropriate chronic HBV patients who may be treatment-naïve or switching[1-6]

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.**

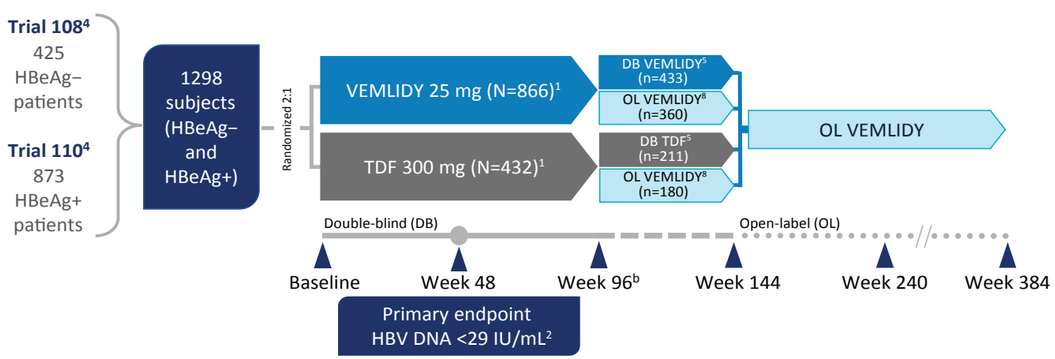
Click here for full Prescribing Information for VEMLIDY, including **BOXED WARNING** on posttreatment severe acute exacerbation of hepatitis B.

Vemlidy®
tenofovir alafenamide 25mg tablets

The efficacy and safety of VEMLIDY were evaluated in 2 large clinical trials

~75% of patients in pivotal Trials 108/110 were treatment-naïve[4]

Efficacy and safety of VEMLIDY in the treatment of adults with chronic HBV infection with compensated liver disease are based on data from 2 randomized, double-blind, active-controlled, noninferiority trials.[2,7,a]



[a]Key inclusion criteria: HBV DNA ≥20,000 IU/mL; alanine aminotransferase (ALT) >60 U/L (males) or >38 U/L (females) and ≤10x upper limit of normal (ULN) by central laboratory range.[2,7]

[b]The numbers of patients listed after Week 96 refer to those who entered the open-label phase or remained in the double-blind phase, and excludes patients who prematurely discontinued double-blind study treatment by Week 96.[5,8]

The primary endpoint for both studies was HBV DNA <29 IU/mL and noninferiority to TDF (10% margin; 95% confidence interval [CI] approach) at Week 48.[2,7]

- Additional efficacy endpoints evaluated at Week 48, Week 96, and Week 144 for both trials included the proportion of patients with HBV DNA <29 IU/mL, ALT normalization, and hepatitis B surface antigen (HBsAg) loss and seroconversion. Hepatitis B envelope antigen (HBeAg) loss and seroconversion were also assessed in Trial 110[1,5,7]
- The original protocol was amended to extend the double-blind phase from 96 weeks to 144 weeks. However, before implementation of the amendment protocol, 540 patients entered the open-label phase at Week 96 (360 remained on VEMLIDY and 180 switched from TDF to VEMLIDY)[5]
- By Week 144, a total of 1157 patients had entered the open-label phase[4]
- At Week 384, the full analysis set included 1298 patients who were enrolled in the study[4]

The 8-year analysis is not presented in the VEMLIDY full Prescribing Information.

IMPORTANT SAFETY INFORMATION (CONT.)

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 coinfected 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 coinfected patients should be used.

Click here for full Prescribing Information for VEMLIDY, including **BOXED WARNING**.

VEMLIDY was studied in a broad range of adult patients with chronic HBV

	Pooled population	
Baseline characteristics[1,4,5,7]	**VEMLIDY** (n=866)	**TDF** (n=432)
Age, years, mean (SD)	**40** (11.8)	41 (12.3)
Male, n (%)	**544** (63)	275 (64)
Asian, n (%)	**687** (79)	333 (77)
HBV genotype A, B, C, D, other,[a] %	**6, 19, 48, 26, 1**	7, 20, 46, 24, 2
Mean HBV DNA, $\log_{10}$ IU/mL, mean (SD)	**7** (1.59)	7 (1.63)
Median ALT, U/L (Q1, Q3)	**80** (56, 123)	80 (53, 130)
History of cirrhosis, n (%)[b]	**65** (10)	38 (12)
Treatment-naïve, n (%)	**655** (76)	324 (75)
Prior oral antiviral therapy, n (%)[c]		
Entecavir	**109** (13)	49 (11)
Lamivudine	**86** (10)	40 (9)
Adefovir dipivoxil	**35** (4)	14 (3)
Telbivudine	**21** (2)	12 (3)
Other[d]	**14** (2)	6 (1)
Hip BMD osteopenia or osteoporosis, n (%)	**267** (31)	133 (31)
Spine BMD osteopenia or osteoporosis, n (%)	**366** (42)	182 (42)

>60% of patients were male[4]

~75% of patients were treatment-naïve[4]

>30% of patients were osteopenic or osteoporotic[4]

Treatment-naïve patients had <12 weeks of previous treatment with any nucleoside/nucleotide analog. Treatment-experienced patients met all entry criteria (including HBV DNA ≥20,000 IU/mL and serum ALT criteria) and had ≥12 weeks of previous treatment with any nucleoside/nucleotide analog.[1,5]

[a]"Other" includes genotypes E, F, H, and unknown.[4]

[b]Excludes patients with missing values.[4]

[c]Excluding interferon and TDF.[5]

[d]"Other" category included clevudine, tenofovir alafenamide, and other oral nucleoside/nucleotide agents.[5]

IMPORTANT SAFETY INFORMATION (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 ≥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.

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.

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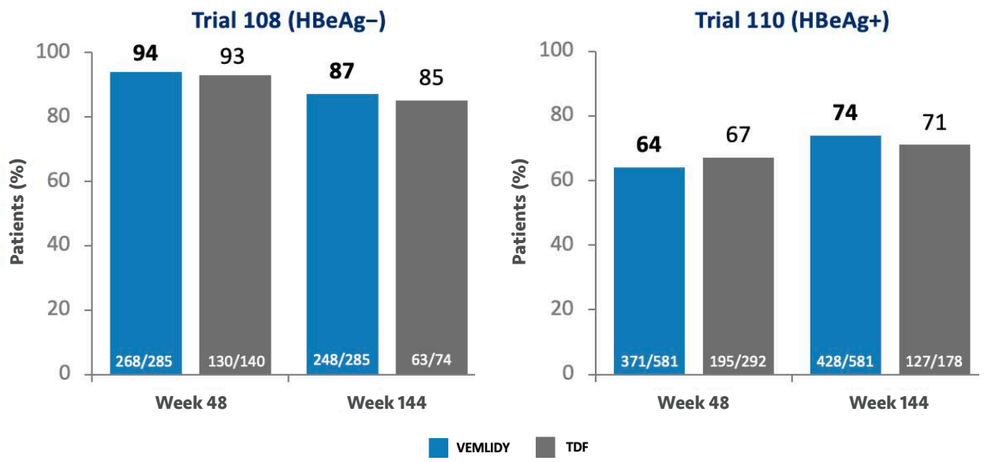
Power of proven efficacy

VEMLIDY demonstrated powerful viral suppression at Weeks 48, 96, and 144 with sustained antiviral efficacy[1-3,6,7]

HBV DNA <29 IU/mL at Weeks 48 and 144[1-3,6,7,a,b]



- Trial 108 viral suppression at Week 96: VEMLIDY 90% (257/285), TDF 91% (127/140)[7]
- Trial 110 viral suppression at Week 96: VEMLIDY 73% (423/581), TDF 75% (218/292)[7]

Mean baseline plasma HBV DNA was 5.8 log_{10} IU/mL in Trial 108 and 7.6 log_{10} IU/mL in Trial 110.[1]

Primary efficacy endpoint: The proportion of patients with HBV DNA <29 IU/mL and noninferiority to TDF (10% margin, 95% CI approach) at Week 48 for both trials.[1-3]

[a]Patient populations analyzed included all treatment-naïve and treatment-experienced patients who were randomized into the trial and received at least 1 dose of study drug; a missing=failure approach was used.[1]
[b]The Week 144 analysis did not include the 66 patients from the TDF group in Trial 108 and the 114 patients from the TDF group in Trial 110 who had rolled over from double-blind TDF to open-label VEMLIDY at Week 96 prior to the study amendment.[5]

IMPORTANT SAFETY INFORMATION (CONT.)

Drug Interactions (cont.)
Consult the full prescribing information for VEMLIDY for more information on potentially significant drug interactions, including clinical comments.

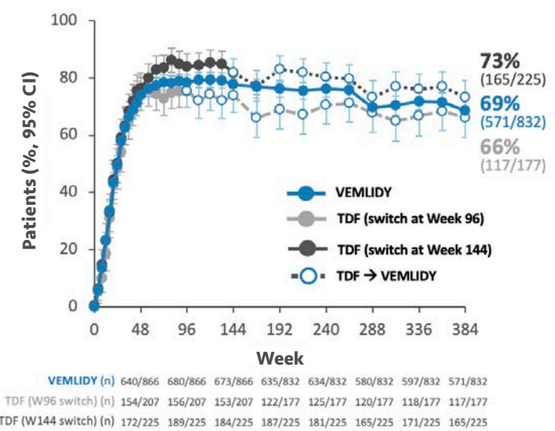
Dosage and Administration
- **Testing Prior to Initiation:** HIV infection.
- **Prior to or When Initiating, and During Treatment:** On a clinically appropriate schedule, assess serum creatinine, estimated creatinine clearance, urine glucose, and urine protein in all patients. In patients with chronic 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.

Click here for full Prescribing Information for VEMLIDY, including **BOXED WARNING**.

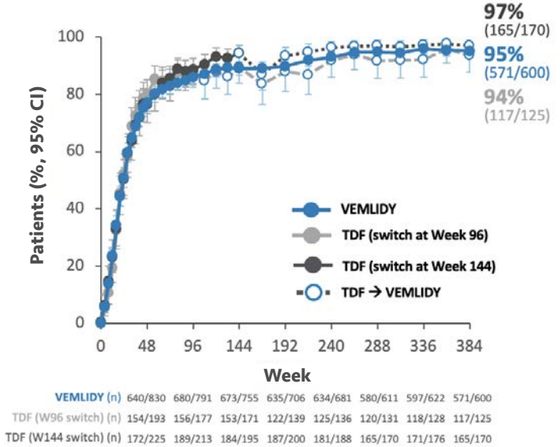
8 years of robust viral suppression with VEMLIDY

Pooled Week 384 analysis: Pooled efficacy analysis from Trials 108 and 110 was assessed at Week 384 analysis for patients in the full analysis set. This analysis included 866 patients who continued on VEMLIDY (pooled), 207 patients who switched from TDF to VEMLIDY at Week 96, and 225 patients who switched from TDF to VEMLIDY at Week 144.[4,a,b]

Missing=Failure (M=F) analysis from Trials 108/110: HBV DNA <29 IU/mL at Year 8[4,5]



Missing=Excluded (M=E) analysis from Trials 108/110: HBV DNA <29 IU/mL at Year 8[4,5]



Due to early study discontinuations, which were mainly not attributable to lack of efficacy or AEs, an M=E approach was performed. In the M=E approach, all missing data were excluded in the computations from this analysis.

Limitations: The M=E data are not powered to show statistical significance and should be considered as descriptive only. Neither the M=E data nor the 8-year data are presented in the VEMLIDY full Prescribing Information.

In an M=E analysis, any patients with missing data are excluded from the final analysis. This approach assumes that the missing data are random and not related to treatment outcomes.

In an M=F analysis, missing values are included. This approach accounts for missing data points as a "failure" in the final analysis.

[a]Mean baseline plasma HBV DNA: 5.8 log_{10} IU/mL in Trial 108 and 7.6 log_{10} IU/mL in Trial 110.[1]
[b]One site did not participate in Protocol amendment 3, and all patients from this site (n=64) discontinued the study on or before Year 3 (Week 144). Therefore, those patients who completed the planned study treatments were excluded from the M=F analysis for all visits after Year 3.[4]

0% resistance

with long-term treatment on VEMLIDY through 8 years[1,4]

In Trials 108 and 110, genotypic resistance analysis was performed on patients experiencing either[1]:
- Virologic breakthrough (2 consecutive visits with HBV DNA ≥69 IU/mL [400 copies/mL] after having been <69 IU/mL, or ≥1.0-log_{10} increase in HBV DNA from nadir)
- Early discontinuation at or after Week 24 with HBV DNA ≥69 IU/mL

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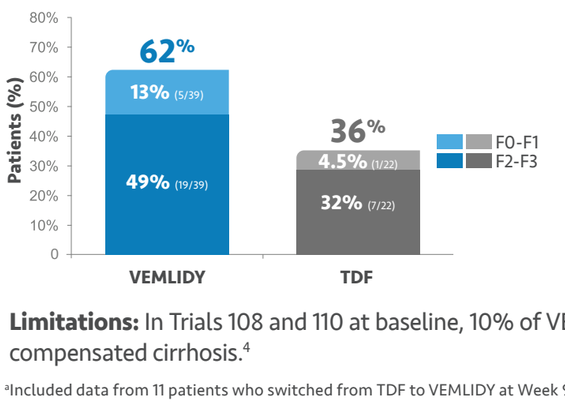
Regression of compensated cirrhosis seen with VEMLIDY through 8 years

Year 3 Data: Among the 1298 randomized and treated patients, 644 remained in the double-blind phase at Week 144, and 398 patients from the VEMLIDY group and 193 patients from the TDF group had FibroTest data available for analysis at both baseline and Week 144. The graphs show the results for those patients who had F4 fibrosis (FibroTest score ≥0.75) at baseline (39 patients in the VEMLIDY group and 22 patients in the TDF group).[5]

Year 8 Data: Among the 1298 randomized and treated patients, 575 patients from the VEMLIDY→VEMLIDY group and 282 patients from the TDF→VEMLIDY groups had FibroTest data available for analysis at both baseline and Week 384. The graphs show the results for those patients who had F4 fibrosis (FibroTest score ≥0.75) at baseline (47 patients in the VEMLIDY→VEMLIDY group and 31 patients in the TDF→VEMLIDY groups).[4]

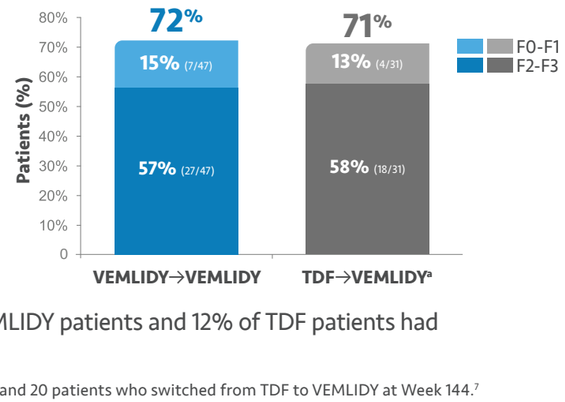
Year 3 (Week 144) Double-Blind Data

Patients with improvement from F4 to F2-F3 or F0-F1 fibrosis



Year 8 (Week 384) OLE Data

Patients with improvement from F4 to F2-F3 or F0-F1 fibrosis



Limitations: In Trials 108 and 110 at baseline, 10% of VEMLIDY patients and 12% of TDF patients had compensated cirrhosis.[4]

[a]Included data from 11 patients who switched from TDF to VEMLIDY at Week 96 and 20 patients who switched from TDF to VEMLIDY at Week 144.[7]

Additional context regarding the data presented on these pages

Change from baseline in fibrosis assessed by FibroTest score (missing=excluded analysis) for VEMLIDY vs TDF was a secondary endpoint in Trials 108 and 110. Liver biopsies and FibroScan® tests were not conducted as part of Trials 108 and 110.[2,3]

FibroTest is a noninvasive measure of liver fibrosis and combines 5 standard biomarkers: gamma-glutamyl transpeptidase, total bilirubin, alpha-2-macroglobulin, apolipoprotein A1, and haptoglobin. Note that FibroTest does not include ALT. FibroTest has been validated for assessing fibrosis in patients with chronic HBV.[9]

The clinical relevance of these changes in FibroTest scores is not known.

This analysis is not presented in the VEMLIDY full Prescribing Information.

Cirrhosis and fibrosis analyses are not powered for statistical significance, and data should be considered descriptive only.

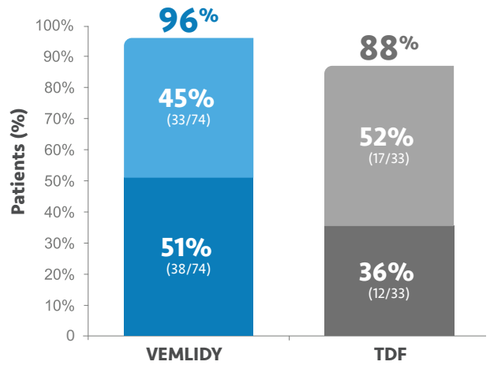
Click here for full Prescribing Information for VEMLIDY, including **BOXED WARNING**.

Regression or halting of fibrosis progression seen with VEMLIDY through 8 years

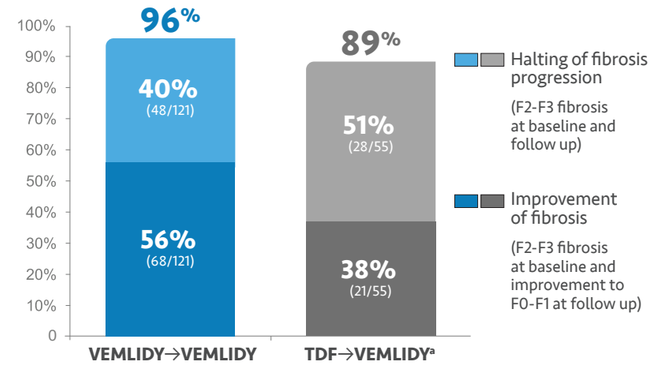
Year 3 Data: Among the 1298 randomized and treated patients, 644 remained in the double-blind phase at Week 144, and 398 patients from the VEMLIDY group and 193 patients from the TDF group had FibroTest data available for analysis at both baseline and Week 144. The graphs show the results for those patients who had F2-F3 fibrosis (FibroTest scores of 0.49-0.74) at baseline (74 patients in the VEMLIDY group and 33 patients in the TDF group).[5]

Year 8 Data: Among the 1298 randomized and treated patients, 575 patients from the VEMLIDY→VEMLIDY group and 282 patients from the TDF→VEMLIDY groups had FibroTest data available for analysis at both baseline and Week 384. The graphs show the results for those patients who had F2-F3 fibrosis (FibroTest scores of 0.49-0.74) at baseline (121 patients in the VEMLIDY→VEMLIDY group and 55 patients in the TDF→VEMLIDY groups).[4]

Year 3 (Week 144) Double-Blind Data



Year 8 (Week 384) OLE Data



Limitations: In Trials 108 and 110 at baseline, 20% of VEMLIDY patients and 19% of TDF patients had F2-F3 fibrosis.[4] Please see additional context regarding the limitations.

[a]Included data from 29 patients who switched from TDF to VEMLIDY at Week 96 and 26 patients who switched from TDF to VEMLIDY at Week 144.[4]

IMPORTANT SAFETY INFORMATION (CONT.)

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.

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 coinfected 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 coinfected patients should be used.

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VEMLIDY demonstrated a well-established safety profile for a broad range of patient types from pivotal trials through 8 years*

Trials 108 and 110 (pooled)

The proportion of patients who discontinued treatment at Week 96 due to adverse reactions (ARs) of any severity was 1.5% with VEMLIDY and 0.9% with TDF.[1] At Week 144, the discontinuation rates due to ARs of any severity were 1.6% with VEMLIDY and 1.6% with TDF.[1,5]

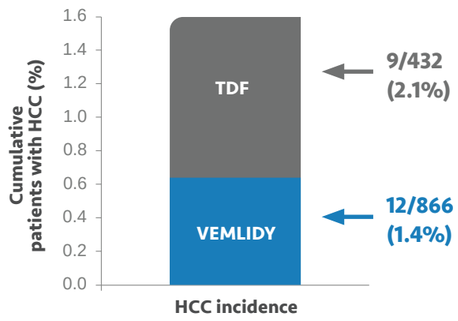
Adverse reactions[a] (all grades) reported in ≥5% of patients on VEMLIDY in Trials 108 and 110 (Week 96 and Week 144 analyses)

	VEMLIDY pooled population (n=866)	
Adverse reactions[1,5,7]	**Week 96**	**Week 144**
Headache	12%	13%
Upper respiratory tract infection	11%	13%
Abdominal pain[b]	9%	10%
Cough	8%	9%
Back pain	6%	7%
Fatigue	6%	7%
Nausea	6%	7%
Arthralgia	5%	7%
Diarrhea	5%	6%
Dyspepsia	5%	5%
Pyrexia	5%	5%

Pooled safety analysis (Week 384) of 1157 patients who completed the double-blind treatment and entered the VEMLIDY open-label extension[4]

- Incidence ≥5% (all grades) were headache, upper respiratory tract infection, nasopharyngitis, hypertension, arthralgia, cough, and back pain

At Week 384, **21 cases (1.6% incidence)** of hepatocellular carcinoma (HCC) were observed in Trials 108 and 110.[4,a,c]



HCC surveillance was included as part of the 96-week protocol amendments for Trials 108/110. These trials were not powered to look at any treatment effect on HCC, and no results should be drawn based on these observations. This information is not in the VEMLIDY Prescribing Information.[5]

*See page 3 for the baseline characteristics of the broad range of patients in the VEMLIDY trials.
[a]Frequencies of adverse reactions are based on all treatment-emergent adverse events, regardless of relationship to study drug.[1]
[b]Grouped term including abdominal pain upper, abdominal pain, abdominal pain lower, and abdominal tenderness.[1]
[c]3 cases of HCC were observed in the open-label TDF→VEMLIDY group, all of which developed before Week 48 of the open-label phase.[5]

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.

Click here for full Prescribing Information for VEMLIDY, including **BOXED WARNING**.

For appropriate chronic HBV patients with compensated liver disease who may need to start or switch treatment

Choose VEMLIDY—backed by proven efficacy and safety data at 48 weeks and demonstrated through 8 years (Week 384)

Summary

8 years — **Long-term viral suppression** demonstrated up to 8 years[1-6]

0% — **0% resistance** with long-term treatment through 8 years[1,4]

Cirrhosis and fibrosis regression observed through 8 years[4]

Well-established **safety profile for a broad range of patients**[1-6]

Over **90% of commercially insured patients enrolled pay $0*** with the Co-pay Coupon Program[a]


Actor portrayal.

*Co-pay coupon support is available for commercially insured eligible patients only. Additional restrictions may apply. Subject to change; for full terms and conditions, visit www.mysupportpath.com/providers. This is not health insurance. Only accepted at participating pharmacies
[a]Data on File as of August 2024, VEMLIDY Co-pay Coupon Program. Gilead Sciences, Inc.

See complete analyses of the summary data on previous pages.

References: 1. VEMLIDY Prescribing Information, Foster City, CA: Gilead Sciences, Inc.; March 2024. **2.** Chan HL, Fung S, Seto WK, et al. Tenofovir alafenamide versus tenofovir disoproxil fumarate for the treatment of HBeAg-positive chronic hepatitis B virus infection: a randomised, double-blind, phase 3, non-inferiority trial. *Lancet Gastroenterol Hepatol.* 2016;1(3):185-195. **3.** Buti M, Gane E, Seto WK, et al. Tenofovir alafenamide versus tenofovir disoproxil fumarate for the treatment of patients with HBeAg-negative chronic hepatitis B virus infection: a randomised, double-blind, phase 3, non-inferiority trial. *Lancet Gastroenterol Hepatol.* 2016;1(3):196-206. **4.** Buti M, Lim YS, Chan HLY, et al. Eight-year efficacy and safety of tenofovir alafenamide for treatment of chronic hepatitis B virus infection: Final results from two randomised phase 3 trials. *Alimentary Pharmacology & Therapy.* 2024;00:5, Table 1. **5.** Data on file. Gilead Sciences, Inc. **6.** Chan HLY, Lim YS, Seto WKW, et al. 3-year efficacy and safety of tenofovir alafenamide compared with tenofovir disoproxil fumarate in HBeAg-negative and -positive patients with chronic hepatitis B. Poster presented at: AASLD 2018; November 9-13, 2018; San Francisco, CA. Poster 381. **7.** Agarwal K, Brunetto M, Seto WK, et al. 96 weeks treatment of tenofovir alafenamide vs tenofovir disoproxil fumarate for hepatitis B virus infection. *J Hepatol.* 2018;68(4):672-681. doi: 10.1016/j.jhep.2017.11.039 **8.** Chan HLY, Buti M, Agarwal K, et al. Maintenance of high levels of viral suppression and improved safety profile of tenofovir alafenamide relative to tenofovir disoproxil fumarate in chronic hepatitis B patients treated for 5 years in 2 ongoing phase 3 studies. Poster presented at AASLD 2020; November 13-16; virtual. Poster 803. **9.** Parikh P, Ryan JD, Tsochatzis EA. Fibrosis assessment in patients with chronic hepatitis B virus (HBV) infection. *Ann Transl Med.* 2017;5(3):40. doi: 10.21037/atm.2017.01.28

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Broad coverage and resources for your appropriate patients

As low as

$0* co-pay

The VEMLIDY Co-pay Coupon Program may help your eligible, commercially insured patients lower their out-of-pocket costs

Over 90% of commercially insured patients enrolled pay $0* with the VEMLIDY Co-pay Coupon Program.†

Support Path®

Do your patients worry about cost? Insurance or no insurance, Support Path may be able to help.

Support Path provides information to help facilitate patient access to medication. Whether they have insurance or not, Support Path can explore potential coverage options that might be right for them. In some cases, patient consent is required before Support Path can provide assistance.

Support Path can provide information on the following topics:

- Benefits investigation
- Prior authorization and appeals process information
- Patient Assistance Program for eligible uninsured patients
- Co-pay Coupon Program*

For multilingual assistance call: 1-855-769-7284, Monday-Friday, 9 AM to 8 PM

*Co-pay coupon support is available for commercially insured eligible patients only. Additional restrictions may apply. Subject to change; for full terms and conditions, visit www.mysupportpath.com/providers. This is not health insurance. Only accepted at participating pharmacies.

†Data on File as of August 2024, VEMLIDY Co-pay Coupon Program. Gilead Sciences, Inc.

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IMPORTANT SAFETY INFORMATION (CONT.)

Adverse Reactions

Most common adverse reactions (incidence ≥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.

GILEAD