# It's about the moments

Continue enjoying moments with loved ones, while treating your chronic hepatitis B



Talk to your healthcare provider today about starting VEMLIDY

VEMLIDY is a prescription medicine that treats chronic (long-lasting) hepatitis B virus (HBV) in adults with stable (compensated) liver disease



## **Every moment is precious with your family and friends**

#### What is VFMI IDY?

VEMLIDY is a prescription medicine used to treat chronic (long-lasting) hepatitis B virus (HBV) in adults with stable (compensated) liver disease.

- VEMLIDY may lower the amount of HBV in your body
- VEMLIDY may improve the condition of your liver

## What important information should I know about VEMLIDY?

VEMLIDY can cause serious side effects, including:

Worsening of hepatitis B virus (HBV) infection.
 Your HBV infection may get worse (flare-up) if you take VEMLIDY and then stop taking it. A "flare-up" is when your HBV infection suddenly returns in a worse way than before. Do not stop taking VEMLIDY without first talking to your healthcare provider, as they will need to monitor your health regularly to check your liver.

### **Timeline of FDA Approvals**

Below is a timeline of oral antiviral treatments for chronic hepatitis B



2002 ADV (adefovir dipivoxil)

2005 ETV (entecavir)

2006 LdT (telbivudine)

**2008 TDF** (tenofovir disoproxil fumarate)

**2016 VEMLIDY** (tenofovir alafenamide)

This timeline is not intended to compare the efficacy or safety of the medications listed above.





### Understanding chronic hepatitis B

### What does the liver do?

The liver is one of the most important parts of the body. It does a lot of things that help you every day, including:



**Fighting infection** 



Storing energy and nutrients



Helping digest food



Removing harmful substances from the blood

### What is chronic hepatitis B?

Chronic hepatitis B is a disease caused by long-term infection by the hepatitis B virus. Over time, it can lead to serious liver damage, such as fibrosis (scarring) or liver cancer.

The higher your viral load, the higher the risk for you to develop liver damage.



It's important to know that you cannot get hepatitis B from touching, kissing, drinking alcohol, food, water, air, or sharing cups and utensils.

### How chronic hepatitis B can damage the liver

The longer your hepatitis B is left untreated, the more damage it can cause.

### Chronic hepatitis B can lead to:



**Inflammation** 

Swelling of the liver that can cause scarring over time



#### **Fibrosis**

Scarring of the liver where scar tissue replaces healthy tissue



#### Cirrhosis

Severe scarring that may affect how the liver works



#### Liver cancer

Also known as hepatocellular carcinoma, or HCC

## Common tests your healthcare provider may order to monitor chronic hepatitis B include:



#### **Viral Load Test**

Measures how much hepatitis B virus is in your body



#### **ALT Test**

Shows whether or not you have active liver damage



#### **Liver Cancer Screening**

Uses an ultrasound image of your liver and/or a blood test to see if there are any cancer cells

ALT=alanine aminotransferase.

### Symptoms of chronic hepatitis B infection

If you feel any of the following symptoms, do not ignore them and make sure to tell your healthcare provider.



Tiredness/ fatigue





Joint pain



Stomach pain



Nausea and vomiting



Loss of appetite



Yellow eyes or skin (known as jaundice)



Light-colored stools or dark urine



Many patients with chronic hepatitis B may not experience any symptoms. Because of the risk for severe liver damage, it is important to see your healthcare provider regularly, even if you feel fine.

Regardless of where you are in your hepatitis B journey, actively managing your hepatitis B is critical. Make sure to see your healthcare provider regularly to monitor your hepatitis B.

### Objectives of antiviral therapy



**Decrease** the amount of **hepatitis B** virus in your body



Reduce damage to the liver



Decrease the chance of developing serious liver diseases, such as cirrhosis and liver cancer

# Treatment for your chronic hepatitis B is important to reduce health issues

If you have chronic hepatitis B, you may have a higher risk of developing other health issues compared to people who don't have the infection.

### Some common health issues include:

- Chronic kidney disease
- Weak bones
- High blood pressure
- Liver cancer

Diabetes

Most patients will need to be on long-term medication since hepatitis B is a chronic disease

# VEMLIDY trial participants followed from initiation through 8 years (Week 384)

As of April 25, 2024, Trial 110 was one of the largest, well-controlled treatment studies in chronic hepatitis B, with 873 patients

 Trials 108 (425 patients) and 110 (873 patients) studied the efficacy and safety of VEMLIDY (25 mg daily) for patients with chronic hepatitis B virus with stable liver disease versus tenofovir disoproxil fumarate (TDF, 300 mg daily)



# **VEMLIDY** was studied in a diverse group of patients

Trials 108 and 110 included patients who were Asian, Black or African American, Native Hawaiian, Pacific Islander, or White

- Patients were 18 to 80 years old
- 63% were male, 37% were female
- 75% of patients had not been on an HBV treatment before

### **Common side effects for VEMLIDY**

The results were analyzed when everyone had been in the study for at least 2 years (~96 weeks). At that point, common side effects\* included:

	<b>VEMLIDY</b> (866 patients)	<b>TDF</b> (432 patients)
Headache	12%	10%
Stomach discomfort <sup>†</sup>	9%	6%
Cough	8%	8%
Back pain	6%	6%
Fatigue	6%	5%
Nausea	6%	6%
Arthralgia (joint pain)	5%	6%
Diarrhea	5%	5%
Dyspepsia (indigestion)	5%	5%

 $<sup>^{*}\</sup>text{Common side}$  effects include any reported in 5% or more of study participants taking VEMLIDY.

### **VEMLIDY** was shown to:



## Reduce the amount of hepatitis B in patients (viral load)

VEMLIDY was found to be **just as effective** as TDF in lowering HBV DNA levels in the body after 48 weeks on therapy:

Trial 108		Trial 110		
<b>VEMLIDY</b>	TDF	<b>VEMLIDY</b>	TDF	
(268 of 285 patients)	(130 of 140 patients)	(371 of 581 patients)	(195 of 292 patients)	
94%	93%	64%	67%	

- Trial 108 HBV DNA lowering at Week 96: VEMLIDY 90% (257 of 285 patients), TDF 91% (127 of 140 patients)
- Trial 110 HBV DNA lowering at Week 96: VEMLIDY 73% (423 of 581 patients), TDF 75% (218 of 292 patients)



### Improve liver-related lab values

ALT is a measure of liver damage. The trials also looked to see if treatment helped ALT levels return to normal and found that **more patients showed normalization on VEMLIDY** after 48 weeks:

Trial 108		Trial 110		
	<b>VEMLIDY</b>	TDF	<b>VEMLIDY</b>	TDF
	(137 of 276 patients) <b>50%</b>	(44 of 138 patients) <b>32%</b>	(257 of 572 patients) <b>45%</b>	(105 of 290 patients) <b>36%</b>

- Trial 108 ALT normalization at Week 96: VEMLIDY 50% (139 of 276 patients), TDF 40% (55 of 138 patients)
- Trial 110 ALT normalization at Week 96: VEMLIDY 52% (299 of 572 patients), TDF 42% (121 of 290 patients)

For details on additional data points up to Week 384 please talk to your healthcare provider.



<sup>†</sup>Stomach discomfort can mean abdominal or gastrointestinal pain or discomfort.

### What are the possible side effects of VEMLIDY?

- New or worse kidney problems, including kidney failure.
   Your healthcare provider should do blood and urine tests to check your kidneys when starting and during treatment with VEMLIDY. Your healthcare provider may tell you to stop taking VEMLIDY if you develop new or worse kidney problems.
- Too much lactic acid in your blood (lactic acidosis), which is a serious but rare medical emergency that can lead to death. Tell your healthcare provider right away if you get these symptoms: weakness or being more tired than usual, unusual muscle pain, being short of breath or fast breathing, stomach pain with nausea and vomiting, cold or blue hands and feet, feeling dizzy or lightheaded, or a fast or abnormal heartbeat.
- **Severe liver problems**, which in rare cases can lead to death. Tell your healthcare provider right away if you get these symptoms: skin or the white part of your eyes turns yellow, dark "tea-colored" urine, light-colored stools, loss of appetite for several days or longer, nausea, or stomach-area pain.



The most common side effect of VEMLIDY is headache. These are not all the possible side effects of VEMLIDY. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

### What should I tell my healthcare provider before taking VEMLIDY?



All of your medical conditions, including if you have end stage renal disease (ESRD) or HIV-1 infection. Your healthcare provider may test you for HIV infection before starting VEMLIDY. If you have HIV and only take VEMLIDY, the HIV virus may develop resistance and become harder to treat.



If you are pregnant or plan to become pregnant. It is not known if VEMLIDY will harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with VEMLIDY.



If you are breastfeeding or plan to breastfeed. VEMLIDY may pass into your breast milk. Talk with your healthcare provider about the best way to feed your baby.



All the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines may affect how VEMLIDY works. Keep a list of all your medicines and show it to your healthcare provider and pharmacist.



Do not start a new medicine without telling your healthcare provider.

Ask your healthcare provider if it is safe to take VEMLIDY with all of your other medicines.



# The safety of VEMLIDY has been studied in long-term clinical trials and its effect on bone and kidney health is well understood

### **Bone safety**

## VEMLIDY has less impact on bone health than TDF

## In Trials 108 and 110, VEMLIDY had less impact on bone mineral density (BMD) than TDF.

BMD is a good gauge and indicator of bone health. For people taking VEMLIDY in Trials 108 and 110, their bone health was less impacted, and they were better able to maintain BMD, compared with those taking tenofovir disoproxil fumarate (TDF).

Bone health is important, and for most people, our bones continue to grow into our 30s. Whether your bones are still growing or you're more focused on maintaining their strength, VEMLIDY is just as effective as TDF with less impact on bone health.

## Compared with TDF, VEMLIDY had less impact on BMD at approximately 2 years (96 weeks):



## Lumbar spine

VEMLIDY (746 patients) **-0.7%** 

TDF (371 patients)

-2.6%



## Hip bone VEMLIDY |

(740 patients)

**TDF** (369 patients)

-0.3%

-2.5%

Larger negative numbers mean more of a decline in BMD.

BMD is a key indicator of bone health. BMD was measured in study participants when they entered the study and again at approximately 2 years from the start of the study.

The long-term significance of these changes in BMD is not known.

eGFR=estimated glomerular filtration rate.

### Renal safety

# VEMLIDY has less impact on kidney health than TDF

In Trials 108 and 110, patients who took VEMLIDY experienced less impact on certain kidney lab tests than those who took TDF.

In patients taking VEMLIDY, kidney function was better maintained than in those taking TDF as measured by laboratory tests.

Kidneys help keep you healthy by removing waste from your blood. That's why it's important to take care of them. VEMLIDY is just as effective as TDF with less impact on your kidneys.

- VEMLIDY may cause new or worsening kidney problems, including kidney failure. Your healthcare provider should do blood and urine tests to check your kidneys when starting and during treatment with VEMLIDY.
- Your healthcare provider may tell you to stop taking VEMLIDY if you develop new or worse kidney problems.

Compared with TDF, VEMLIDY had less impact on kidney function lab tests at approximately 2 years (96 weeks):

**Kidney** 



VEMLIDY

-1.2%

TDF -4.8%

mL/min eGFR

Larger negative numbers mean more of a decline in kidney function.

eGFR is one of the measurements that your healthcare provider may use to see how your kidneys are functioning. eGFR was measured in study participants when they entered the study and again at approximately 2 years from the start of the study.

The long-term significance of these changes on the frequency of kidney side effects is not known.



# Same convenient, simple dosing every day with VEMLIDY

VEMLIDY is one small\* tablet, taken with food, any time of day without complicated schedules.



Pill image not to scale. (\*8 mm in diameter)



You must take VEMLIDY exactly how your healthcare provider tells you to.



If you are on dialysis, on your dialysis days, take VEMLIDY after dialysis. It's also important to take VEMLIDY on a regular dosing schedule to avoid missing doses.



Do not stop taking VEMLIDY unless your healthcare provider tells you to. If you stop taking your medicine, your HBV infection could get worse (flare-up). A "flare-up" is when your HBV infection suddenly returns in a worse way than before.



It is very important that you refill your prescription on time, before you run out. When your VEMLIDY supply starts to run low, get more from your healthcare provider or pharmacy. This will help make sure that you are not at risk of missing any doses and causing a flare-up.



If you take too much VEMLIDY, call your healthcare provider or go to the nearest hospital emergency room right away.

### Worried about cost?

As low as



You may be eligible for the VEMLIDY Co-pay Coupon Program

The VEMLIDY Co-pay Coupon Program is here to help reduce your out-of-pocket costs

- Out-of-pocket costs will be covered up to \$6,000 each year
- No monthly limit
- For eligible patients who have commercial insurance



**Translation services are available** in a variety of languages.

Please call **1-877-627-0415** today to get started.

\*See specific terms and conditions at mysupportpath.com

**Support Path® is here to help you**, even if you aren't eligible for the VEMLIDY Co-pay Coupon Program

- Do you need help understanding your health insurance and Gilead medication costs?
- Even if you are not eligible for the Co-pay Coupon Program you can call Support Path at the number below to learn about other financial resources that may be available to assist with treatment and insurance costs



For more information call **1-855-7-MYPATH** (1-855-769-7284) **Hours:** Monday-Friday, 9 AM to 8 PM, ET



Please visit www.vemlidy.com/savings for more information on eligibility and how to enroll.



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• Worsening of hepatitis B virus (HBV) infection.

Your HBV infection may get worse (flare-up) if you take VEMLIDY and then stop taking it. A "flare-up" is when your HBV infection suddenly returns in a worse way than before. Do not stop taking VEMLIDY without first talking to your healthcare provider, as they will need to monitor your health regularly to check your liver.

# What should you do next?

Whether you have a prescription or are just starting to think about treatment, it's important to know what to do next.



**Regularly monitor** your hepatitis B



Ask your healthcare provider if VEMLIDY is right for you



**Take VEMLIDY as directed** by your healthcare provider



Visit the links below to hear patient stories and learn more about hepatitis B



to view useful videos from patients like you



to view additional resources

<u>Click here</u> for Important Facts about VEMLIDY, with **important warnings** on **worsening of hepatitis B infection**.

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