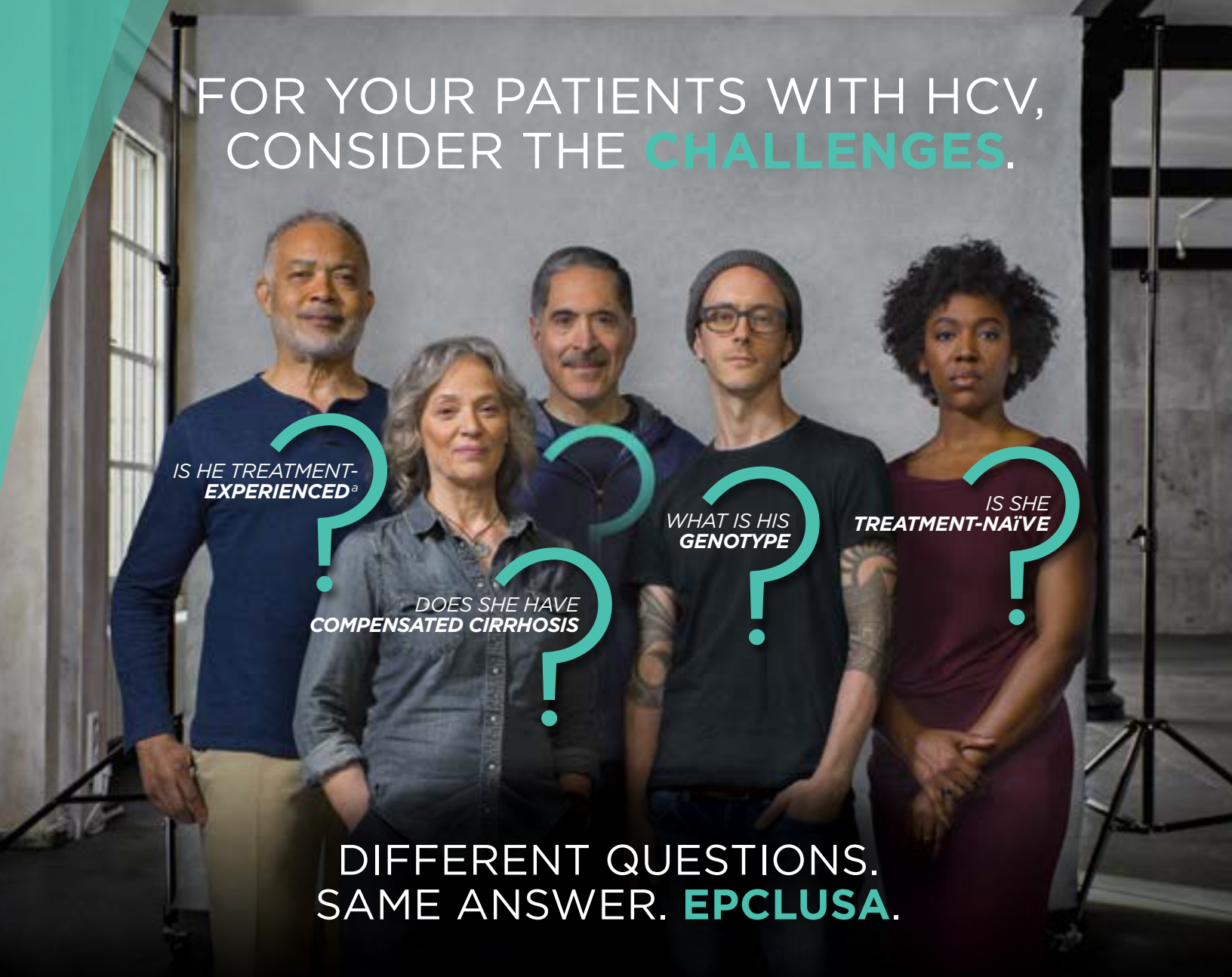
FOR YOUR PATIENTS WITH HCV, CONSIDER THE **CHALLENGES**.



DIFFERENT QUESTIONS. SAME ANSWER. **EPCLUSA**.

[a] In EPCLUSA clinical trials, treatment-experienced patients had failed a Peg-IFN + RBV-based regimen with or without an HCV NS3/4A protease inhibitor (boceprevir, simeprevir, or telaprevir).[1]

Peg-IFN = peginterferon alfa; RBV = ribavirin.

Not actual patients.

INDICATION

EPCLUSA is indicated for the treatment of adults with chronic hepatitis C virus (HCV) GT 1-6 infection without cirrhosis or with compensated cirrhosis.

WARNING: RISK OF HEPATITIS B VIRUS REACTIVATION IN PATIENTS COINFECTED WITH HCV AND HBV: Hepatitis B virus (HBV) reactivation has been reported, in some cases resulting in fulminant hepatitis, hepatic failure, and death.

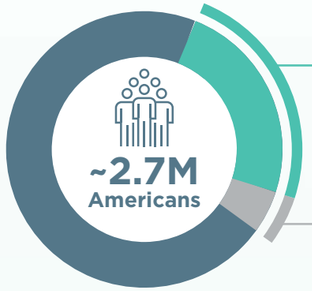
Click here for EPCLUSA full Prescribing Information, including **BOXED WARNING on Hepatitis B reactivation**.

EPCLUSA®
sofosbuvir/velpatasvir
400 mg/100 mg tablets

HCV IS CURABLE, YET IT REMAINS **A SERIOUS HEALTH RISK.**

Cure = sustained virologic response (SVR12; HCV RNA <LLOQ 12 weeks after treatment completion).

2.7 MILLION AMERICANS ARE LIVING WITH CHRONIC HCV INFECTION[2,a]



24% have been **DIAGNOSED**[2]

ONLY **5%** **RECEIVED HCV TREATMENT** in 2018[2]

44k

estimated new acute HCV cases in 2017[3]

INJECTION DRUG USE and the **OPIOID EPIDEMIC** are fueling the new infections[2]

Patients may be asymptomatic, but when left untreated, HCV may lead to **LIVER DAMAGE AND LIFE-THREATENING COMPLICATIONS**[4]

LLOQ = lower limit of quantification.
[a]According to data from 2018.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: RISK OF HEPATITIS B VIRUS REACTIVATION IN HCV/HBV COINFECTED PATIENTS

Test all patients for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with EPCLUSA. HBV reactivation has been reported in HCV/HBV coinfected patients who were undergoing or had completed treatment with HCV direct-acting antivirals (DAAs) and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. Cases have been reported in patients who are HBsAg positive, in patients with serologic evidence of resolved HBV, and also in patients receiving certain immunosuppressant or chemotherapeutic agents; the risk of HBV reactivation associated with treatment with HCV DAAs may be increased in patients taking these other agents. Monitor HCV/HBV coinfected patients for hepatitis flare or HBV reactivation during HCV treatment and post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated.

Click here for EPCLUSA full Prescribing Information, including **BOXED WARNING on Hepatitis B reactivation**.

BY TREATING HCV IN YOUR PRACTICE, **YOU CAN MAKE A DIFFERENCE.**

Many states have reduced prescribing restrictions, leaving only a few that require a specialist to prescribe HCV therapy[5]

Sofosbuvir-based therapies have treated over

900k
PATIENTS WITH HCV[6,b]

Treating HCV can have a positive impact on your patients and your community.
Your patients trust your care. Feel confident knowing cure is possible.[7,8]

[b]12/2013-9/2019.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Serious Symptomatic Bradycardia When Coadministered with Amiodarone:** Amiodarone is not recommended for use with EPCLUSA due to the risk of symptomatic bradycardia, particularly in patients also taking beta blockers or with underlying cardiac comorbidities and/or with advanced liver disease. A fatal cardiac arrest was reported in a patient taking amiodarone who was coadministered a sofosbuvir-containing regimen. In patients without alternative viable treatment options, cardiac monitoring is recommended. Patients should seek immediate medical evaluation if they develop signs or symptoms of bradycardia.
- **Risk of Reduced Therapeutic Effect Due to Concomitant Use of EPCLUSA with P-gp Inducers and/or Moderate to Potent Inducers of CYP2B6, CYP2C8 or CYP3A4:** Rifampin, St. John's wort, and carbamazepine are not recommended for use with EPCLUSA as they may significantly decrease sofosbuvir and/or velpatasvir plasma concentrations.

ADVERSE REACTIONS

- The most common adverse reactions (≥10%, all grades) with EPCLUSA were headache and fatigue.

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sofosbuvir/velpatasvir
400 mg/100 mg tablets

KEY STEPS TO **TREATING HCV**

PRE-TREATMENT **ASSESSMENTS**[9-14]

Clinical Assessment and Considerations

- Conduct a physical examination and obtain a patient history, including HCV treatment history, clinical signs of cirrhosis, extrahepatic manifestations, and all current medications
- Most DAAs are approved for patients with any stage of renal impairment, including those on dialysis

Blood Tests

- HCV genotype for regimens that are not pangenotypic, HCV RNA viral load, CBC, CMP (AST, ALT, bilirubin, albumin, creatinine), HBV, HIV, HAV, INR

Fibrosis Staging

- Estimate fibrosis stage (F0-F4) to assess for the risk of advanced fibrosis/cirrhosis (F3/F4)
  - Calculate the AST-to-platelet ratio index (APRI) and/or FIB-4 score
  - Other noninvasive measures: serum-based fibrosis markers and liver stiffness measurement using elastography or liver imaging studies
- If a patient has been previously treated or there's a potential history of decompensated liver disease, refer to a hepatologist as not all DAAs are indicated for these populations

When choosing a therapy, assess for potential drug-drug interactions

- DDI management will vary depending upon your patient and the selected DAA regimen. For more details, please refer to the DDI comparison in the recent AASLD treatment guidelines

TREATMENT **MONITORING**[9,10,14,15]

- At week 4, consider assessing patient adherence and/or ALT (optional)
- Frequent monitoring of relevant laboratory parameters (INR in patients taking warfarin or blood glucose in diabetic patients treating diabetes) is recommended
- Protease inhibitor-containing regimens: the FDA recommends close monitoring for worsening liver function in patients with advanced liver disease; protease inhibitors are not recommended for patients who have or have had decompensated cirrhosis

TREATMENT **FOLLOW-UP**[9,10,12]

- At 12 weeks post-treatment, confirm a cure by assessing HCV RNA
- Refer patients with detectable HCV RNA or persistently elevated ALT to a specialist
- Counsel on measures to avoid reinfection and further liver damage
- For patients with continued risk, screen HCV RNA annually
- Patients with advanced fibrosis need ongoing HCC surveillance

ALT = alanine aminotransferase; APRI = AST-to-platelet ratio index; AST = aspartate aminotransferase; CBC = complete blood count; CMP = comprehensive metabolic panel; CT = computed tomography; DAA = direct-acting antiviral; DDI = drug-drug interaction; F0-F4 = stage 0-stage 4 fibrosis; F3 = stage 3 fibrosis; F4 = stage 4 fibrosis; FIB-4= Fibrosis-4; HCC = hepatocellular carcinoma; HIV = human immunodeficiency virus; INR = International Normalized Ratio.

Patient Name:_____ DOB:_____ DATE:_____

Chronic Hepatitis C Treatment Checklist

PRE-TREATMENT **ASSESSMENTS**

Clinical assessment

- ○ Conduct a physical examination and obtain a patient history, including prior treatment and cirrhosis status

Blood tests

- ○ HCV genotype if needed
- ○ HCV RNA viral load
- ○ CBC
- ○ CMP
- ○ HIV test
- ○ HBV serology (HBsAg, Anti-HBc, Anti-HBs)

Fibrosis staging

- ○ APRI and/or FIB-4 score
- ○ FibroSure® [550123] FibroTest™ [92688] FibroMeter™ [2005661]
- ○ FibroScan® [91200] or liver imaging (ultrasound, MRI, CT) (if needed)

Assess for potential drug-drug interactions

- ○ When choosing a treatment, assess for potential drug-drug interactions and see AASLD Guidelines for a comprehensive list of interactions with DAAs and select concomitant medications

Treatment Regimen: _____

TREATMENT **MONITORING**

Week 4 check-in (optional)

- ○ Assess patient adherence and/or obtain labs (HCV RNA, ALT)

Ongoing assessment (if applicable)

- ○ Additional monitoring may be required for patients with advanced liver disease

TREATMENT **FOLLOW-UP**

Assessment of cure (12 weeks after therapy completion) (SVR12)

- ○ Confirm a cure by assessing HCV RNA

Patient counseling

- ○ Counsel patients on measures to avoid reinfection and further liver damage

Surveillance

- ○ For patients with continued risk, screen HCV RNA annually

TREAT **WITH EPCLUSA.**

Sofosbuvir/velpatasvir:

THE **ONLY PROTEASE INHIBITOR–FREE** PANGENOTYPIC, PANFIBROTIC HCV REGIMEN[1,16]

CONSISTENT DOSING

One duration, one pill, once a day
12 weeks with or without food[1,a]

BROADEST ACCESS

of any pangenotypic regimen[17,b]

IMPORTANT SAFETY INFORMATION

DRUG INTERACTIONS

- Coadministration of EPCLUSA is not recommended with topotecan due to increased concentrations of topotecan.
- Coadministration of EPCLUSA is not recommended with proton-pump inhibitors, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifapentine, efavirenz, and tipranavir/ritonavir due to decreased concentrations of sofosbuvir and/or velpatasvir.

Consult the full Prescribing Information for EPCLUSA for more information on potentially significant drug interactions, including clinical comments.

Click here for EPCLUSA full Prescribing Information, including **BOXED WARNING on Hepatitis B reactivation**.

Learn more at **HCP.EPCLUSA.COM**

EPCLUSA SUPPORT path®

EPCLUSA Support Path® is a program that can help eligible patients get started on EPCLUSA. Call now to connect live with an EPCLUSA Support Path Program Navigator at 1-855-7-MYPATH (**1-855-769-7284**).

[a]In NC/CC patients.

[b]Based on total covered lives as of October 2019, primarily reflecting the Commercial and Medicare Part D segments. Panfibrotic = stage 0-stage 4 fibrosis (compensated cirrhosis)

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