CURING HEPATITIS C WITH PROVEN EFFICACY AND AN ESTABLISHED SAFETY PROFILE[1]

#1 PRESCRIBED CHRONIC HCV PRODUCT
IQVIA, week ending 1/5/18-4/3/2020.[2]

MAVYRET for Hepatitis C in PWID and Those on MAT[1]

Cure = Sustained virologic response (SVR12); HCV RNA <LLOQ at 12 weeks after the end of treatment.
HCV = Hepatitis C virus; LLOQ = Lower limit of quantification; MAT = Medication-assisted treatment; PWID = People who inject drugs.

INDICATION[1]

MAVYRET is indicated for the treatment of adult and pediatric patients 12 years and older or weighing at least 45 kg with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A). MAVYRET is indicated for the treatment of adult and pediatric patients 12 years and older or weighing at least 45 kg with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor (PI), but not both.

SAFETY CONSIDERATIONS[1]

Test all patients for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with MAVYRET. HBV reactivation has been reported in HCV/HBV coinfected patients who were undergoing or had completed treatment with HCV direct-acting antivirals and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. 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. MAVYRET is contraindicated in patients with moderate or severe hepatic impairment (Child-Pugh B or C) or those with any history of prior hepatic decompensation and with coadministration of atazanavir or rifampin. Postmarketing cases of hepatic decompensation/failure, some fatal, have been reported in patients treated with HCV NS3/4A protease inhibitor-containing regimens, including MAVYRET. The median time to onset for MAVYRET was 27 days. The majority had moderate or severe hepatic impairment prior to initiating therapy, including some with compensated cirrhosis at baseline but with a prior decompensation event. Rare cases were reported in patients without cirrhosis or with compensated cirrhosis; many of these patients had evidence of portal hypertension. In patients with compensated cirrhosis or evidence of advanced liver disease, perform hepatic laboratory testing as clinically indicated; and monitor for signs and symptoms of hepatic decompensation such as the presence of jaundice, ascites, hepatic encephalopathy, and variceal hemorrhage. Discontinue MAVYRET in patients who develop evidence of hepatic decompensation/failure.

Please see additional Important Safety Information, including BOXED WARNING on Hepatitis B Virus reactivation, on page 8 and accompanying full Prescribing Information.

MAVYRET®
glecaprevir/pibrentasvir
100 mg/40 mg tablets

RISK OF HCV INFECTION IN PWID

BETWEEN 2010 AND 2017, THERE WAS ~3X INCREASE IN NEW HCV INFECTIONS[3]

~70% of new HCV infections resulted from injection drug use.[4]

AMONG PEOPLE WITH INJECTION DRUG USE IN THE PREVIOUS 12 MONTHS

40% are living with chronic HCV infection.[5]

AASLD-IDSA HCV TESTING RECOMMENDATIONS

According to AASLD-IDSA[4]:

- One-time, routine, opt-out HCV testing is recommended for all individuals aged 18 years and older
- Annual HCV testing is recommended for all PWID

PWID CONSIDERATIONS FOR HCV TREATMENT

According to AASLD-IDSA[4]:

- Active or recent injection drug use is not a contraindication to HCV therapy
- The rate of HCV reinfection in the PWID population is lower (2.4/100 person-years) than the rate of incident HCV infection in the general population of PWID (6.1-27.2/100 person-years) although the rate of reinfection increases with active or ongoing injection drug use (6.44/100 person-years) and available data on follow-up duration are limited

According to the American Society of Addiction Medicine (ASAM)[6]:

- Active alcohol and/or drug use should not in itself exclude any person from receiving treatment for their HCV infection

AASLD = American Association for the Study of Liver Diseases; IDSA = Infectious Diseases Society of America.
AASLD defines PWID as individuals who are actively using drugs and those who have previously used injection drugs.

METHODOLOGY[1]

PWID

Among 4,655 chronic HCV genotype 1-6-infected adolescents and adults in Phase 2 and 3 trials who received MAVYRET and specified whether or not they had a history of injection drug use, 1,373 subjects were identified as PWID based on self-reported history of injection drug use at trial enrollment and 3,282 subjects did not report injection drug use (non-PWID). Of the PWID population, 62 subjects were considered current/recent PWID (defined as self-reported injection drug use within the last 12 months prior to starting MAVYRET), 959 subjects were considered former PWID (defined as self-reported injection drug use more than 12 months prior to starting MAVYRET), and 352 subjects did not specify current/recent PWID versus former PWID and were not included in the analysis.

MAT for Opioid Use Disorder

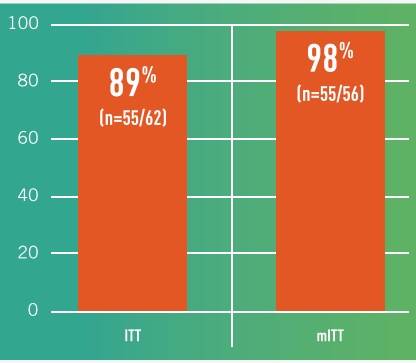
Among 4,655 chronic HCV genotype 1-6-infected adolescents and adults in Phase 2 and 3 trials who received MAVYRET and specified whether or not they had a history of injection drug use, 225 subjects reported concomitant use of MAT for opioid use disorder and 4,098 subjects reported no use of MAT (332 subjects were not included in the analysis due to missing assessment of MAT).

SAFETY CONSIDERATIONS[1]

- MAVYRET is contraindicated in patients with moderate or severe hepatic impairment (Child-Pugh B or C) or those with any history of prior hepatic decompensation.
- MAVYRET is contraindicated with atazanavir or rifampin.

Please see additional Important Safety Information, including BOXED WARNING on Hepatitis B Virus reactivation, on page 8 and accompanying full Prescribing Information.

MAVYRET DEMONSTRATED EFFICACY AND SAFETY IN PWID[1,7]



CURE RATE

89% ITT (SVR12)
- 2% virologic failure (n=1/62)

98% mITT (SVR12)

- In patients reporting injection drug use within the last 12 months who received MAVYRET for 8, 12, or 16 weeks[1]
- **2% treatment discontinuation rate** due to serious adverse reactions and/or adverse reactions
- **Most common adverse reactions** were fatigue (16%), headache (13%), diarrhea (6%), and nausea (6%)

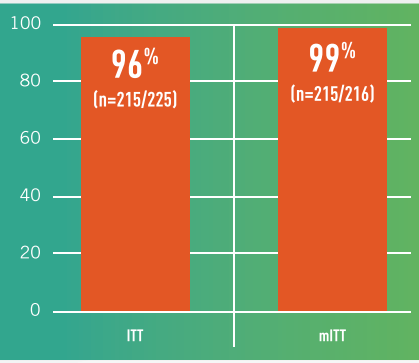
Cure = Sustained virologic response (SVR12); HCV RNA <LLOQ at 12 weeks after the end of treatment.
ITT = Intent-to-treat; mITT = Modified intent-to-treat (excluding patients with non-virologic failure).

NO DOSAGE ADJUSTMENT OF MAVYRET IS REQUIRED IN PWID[1]

Please see Important Safety Information, including BOXED WARNING on Hepatitis B Virus reactivation, on page 8 and accompanying full Prescribing Information.

MAVYRET® glecaprevir/pibrentasvir 100 mg/40 mg tablets

MAVYRET DEMONSTRATED EFFICACY AND SAFETY IN PATIENTS TAKING CONCOMITANT MAT[1,7]



CURE RATE

96% ITT (SVR12)
- 0.4% virologic failure (n=1/225)

99% mITT (SVR12)

- In patients reporting concomitant use of MAT for opioid use disorder with MAVYRET for 8, 12, or 16 weeks[1]
- **No treatment discontinuations** due to serious adverse reactions and/or adverse reactions were observed
- **Most common adverse reactions** were headache (15%), fatigue (12%), nausea (11%), and diarrhea (6%)

NO DOSAGE ADJUSTMENT OF MAVYRET IS REQUIRED IN THOSE ON MAT FOR OPIOID USE DISORDER[1]

- No buprenorphine/naloxone or methadone dosage adjustment is required when used concomitantly with MAVYRET. There is insufficient information to make a recommendation regarding the concomitant use of naltrexone with MAVYRET[1]

SAFETY CONSIDERATIONS[1]

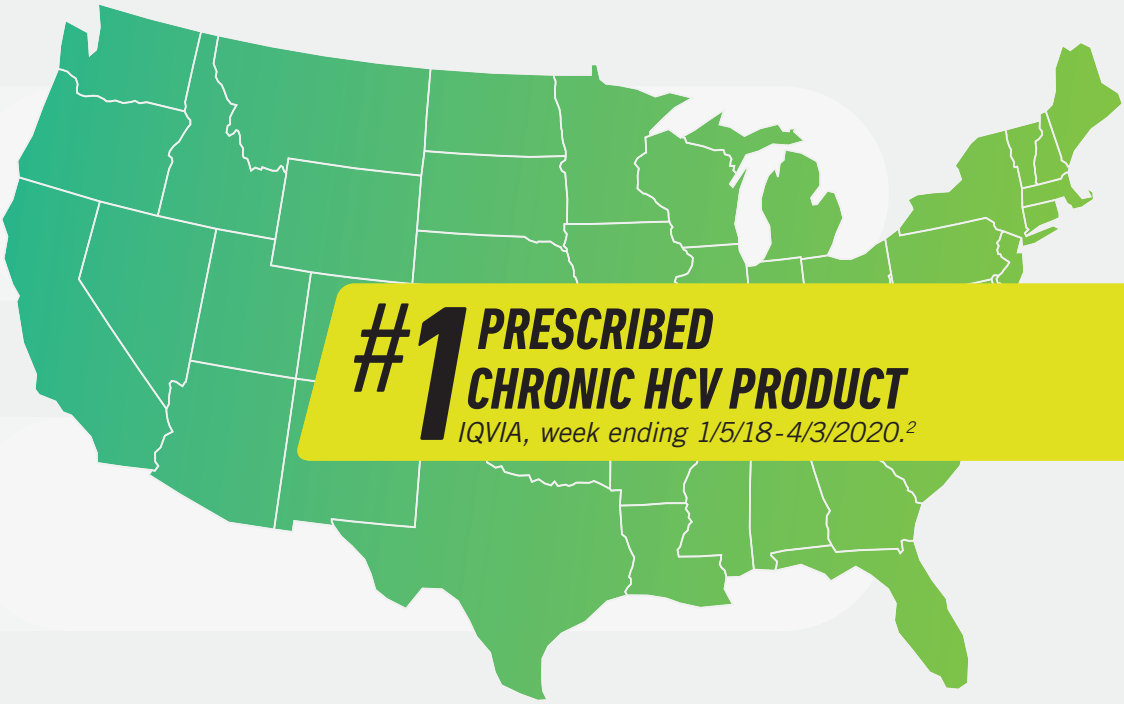
WARNING: RISK OF HEPATITIS B VIRUS REACTIVATION IN PATIENTS COINFECTED WITH HCV AND HBV: Test all patients for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with MAVYRET. HBV reactivation has been reported in HCV/HBV coinfected patients who were undergoing or had completed treatment with HCV direct-acting antivirals and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. 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.

Please see additional Important Safety Information, including BOXED WARNING on Hepatitis B Virus reactivation, on page 8 and accompanying full Prescribing Information.

MAVYRET® glecaprevir/pibrentasvir 100 mg/40 mg tablets

MAVYRET HAS BROAD FORMULARY COVERAGE[8]

- **MAVYRET has preferred formulary status on the majority of Medicare Part D plans**
- **MAVYRET has preferred formulary status on the majority of state Medicaid plans**
- **MAVYRET has preferred formulary status on the majority of national commercial health plans**



Coverage requirements and benefit designs vary by payer and may change over time. Please consult with payers directly for the most current reimbursement policies.

Preferred means the product is placed on the plan's preferred formulary. Nonpreferred products require a higher out-of-pocket cost or step edit, or are placed on a higher tier.

Please see Important Safety Information, including BOXED WARNING on Hepatitis B Virus reactivation, on page 8 and accompanying full Prescribing Information.

MAVYRET® glecaprevir/pibrentasvir 100 mg/40 mg tablets

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION[1]

MAVYRET is indicated for the treatment of adult and pediatric patients 12 years and older or weighing at least 45 kg with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A). MAVYRET is indicated for the treatment of adult and pediatric patients 12 years and older or weighing at least 45 kg with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor (PI), but not both.

IMPORTANT SAFETY INFORMATION[1]

WARNING: RISK OF HEPATITIS B VIRUS REACTIVATION IN PATIENTS COINFECTED WITH HCV AND HBV: Test all patients for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with MAVYRET. HBV reactivation has been reported in HCV/HBV coinfected patients who were undergoing or had completed treatment with HCV direct-acting antivirals and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. 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.

CONTRAINDICATIONS

- MAVYRET is contraindicated in patients with moderate or severe hepatic impairment (Child-Pugh B or C) or those with any history of prior hepatic decompensation.
- MAVYRET is contraindicated with atazanavir or rifampin.

WARNINGS AND PRECAUTIONS

Risk of Hepatic Decompensation/Failure in Patients with Evidence of Advanced Liver Disease

- Postmarketing cases of hepatic decompensation/failure, some fatal, have been reported in patients treated with HCV NS3/4A protease inhibitor-containing regimens, including MAVYRET. The median time to onset for MAVYRET was 27 days. The majority had moderate or severe hepatic impairment prior to initiating therapy, including some with compensated cirrhosis at baseline but with a prior decompensation event. Rare cases were reported in patients without cirrhosis or with compensated cirrhosis; many of these patients had evidence of portal hypertension. In patients with compensated cirrhosis or evidence of advanced liver disease, perform hepatic laboratory testing as clinically indicated; and monitor for signs and symptoms of hepatic decompensation such as the presence of jaundice, ascites, hepatic encephalopathy, and variceal hemorrhage. Discontinue MAVYRET in patients who develop evidence of hepatic decompensation/failure.

Risk of Reduced Therapeutic Effect Due to Concomitant Use of MAVYRET with Certain Drugs

- Carbamazepine, efavirenz, and St. John's Wort may significantly decrease plasma concentrations of glecaprevir and pibrentasvir, leading to reduced therapeutic effect of MAVYRET. The use of these agents with MAVYRET is not recommended.

ADVERSE REACTIONS

Most common adverse reactions observed with MAVYRET:

- >10% of subjects: headache and fatigue

MAVYRET® glecaprevir/pibrentasvir 100 mg/40 mg tablets

 Please see accompanying full Prescribing Information.

CURING HEPATITIS C WITH PROVEN EFFICACY AND AN ESTABLISHED SAFETY PROFILE

#1 PRESCRIBED CHRONIC HCV PRODUCT
IQVIA, week ending 1/5/18–11/29/19[2]

EFFICACY AND SAFETY

MAVYRET demonstrated efficacy and safety in PWID and patients taking concomitant MAT for opioid use disorder[1]

BROAD COVERAGE

MAVYRET has broad formulary coverage[8]

Coverage requirements and benefit designs vary by payer and may change over time. Please consult with payers directly for the most current reimbursement policies.

Cure = Sustained virologic response (SVR12); HCV RNA <LLOQ at 12 weeks after the end of treatment.

SAFETY CONSIDERATIONS[1]

WARNING: RISK OF HEPATITIS B VIRUS REACTIVATION IN PATIENTS COINFECTED WITH HCV AND HBV: Test all patients for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with MAVYRET. HBV reactivation has been reported in HCV/HBV coinfected patients who were undergoing or had completed treatment with HCV direct-acting antivirals and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. 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.

References: 1. MAVYRET [package insert]. North Chicago, IL: AbbVie Inc.; 2020. **2.** Data on file, AbbVie Inc. IQVIA. National Prescription Audit (NPA), National Prescription Audit Market Dynamics (NPA MD) and Weekly Sales Perspective (WSP) week ending 1/5/2018 to week ending 4/3/2020, Longitudinal Prescription Claims (LRx) week ending 1/5/2018 to week ending 3/27/2020. May 2020. (IQVIA, all rights reserved). **3.** Centers for Disease Control and Prevention. Surveillance for viral hepatitis – United States, 2017. https://www.cdc.gov/hepatitis/statistics/2017surveillance/index.htm. Updated November 14, 2019. Accessed July 15, 2020. **4.** The American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. HCV guidance: recommendations for testing, managing, and treating hepatitis C. www.hcvguidelines.org. Updated November 6, 2019. Accessed July 15, 2020. **5.** Grebely J, Larney S, Peacock A, et al. Global, regional, and country-level estimates of hepatitis C infection among people who have recently injected drugs. *Addiction*. 2019;114(1):150-166. **6.** American Society of Addiction Medicine. Public Policy Statement on Hepatitis C Infection. https://www.asam.org/advocacy/find-a-policy-statement/view-policy-statement/public-policy-statements/2017/04/11/hepatitis-c. Adopted April 7, 2017. Accessed July 15, 2020. **7.** Data on file. ABVRRTI70373. AbbVie Inc.; 2020. **8.** Data on file. AbbVie Inc. Source: Managed Markets Insight & Technology, LLC MMIT Analytics™ as of September 2019, and is subject to change.

Please see additional Important Safety Information, including BOXED WARNING on Hepatitis B Virus reactivation, on page 8 and accompanying full Prescribing Information.

MAVYRET®
glecaprevir/pibrentasvir
100 mg/40 mg tablets

abbvie