Glecaprevir / Pibrentasvir (MAVYRET)
Criteria for Use
Updated June 2024

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES. The Product Information should be consulted for detailed prescribing information.

See the VA National Formulary Committee Monograph on this drug at the *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive glecaprevir / pibrentasvir (GLE/PIB)

- ☐ Limited life expectancy
- ☐ Documented ongoing nonadherence to prescribed medications or medical treatment
- ☐ Concurrent use of drugs not recommended with GLE/PIB (e.g., rifampin, atazanavir, darunavir, efavirenz, etravirine or ritonavir). Recommend full drug-drug interaction check.[1]
- ☐ Severe hepatic impairment (Child-Pugh B/C or history of hepatic decompensation)
- ☐ Prior hepatitis C virus (HCV) treatment failure of both an NS3/4A protease inhibitor AND an NS5A inhibitor
- ☐ Hepatitis B surface antigen (HBsAg) positive and not on antiviral treatment with entecavir or tenofovir
- ☐ Contraindication to ribavirin (RBV) IF RBV is indicated[2]

Inclusion Criteria

All of the following must be met

- ☐ Care is provided by or in consultation with a VA/VA Community Care Hepatitis C Specialist
- ☐ Treatment regimen and duration consistent with HCV genotype (GT) and patient characteristics according to VA HCV Treatment considerations[3]
- ☐ HCV GT 1-6 or ungenotyped but detectable HCV RNA
- ☐ Completed hepatitis B screening: at minimum HBsAg, HBV core antibody (anti-HBc) and HBV surface antibody (anti-HBs)
- ☐ Adherence counseling performed including laboratory follow-up and documented understanding by patient

Additional Inclusion Criteria

One of the following must be true

- ☐ GT 1-6 or ungenotyped but detectable HCV RNA with or without compensated cirrhosis and are treatment naïve
- ☐ GT 1-6 with or without compensated cirrhosis with prior treatment experience with pegylated interferon, ribavirin +/- sofosbuvir (SOF)
- ☐ GT 1 with or without compensated cirrhosis and prior NS3/4A experience (but SOF and NS5A naïve)
- ☐ GT 1 with or without compensated cirrhosis and prior NS5A inhibitor experience but NS3/4A naïve
- ☐ With SOF and RBV for GT 1-6 with or without compensated cirrhosis and treatment experienced with sofosbuvir / velpatasvir / voxilaprevir or SOF plus GLE/PIB[2]

Supplemental Information

Footnotes

[1]See product labeling, HCV Treatment considerations or Liverpool HEP drug interaction checker for complete drug-drug interactions

[2] Contraindication to RBV include history of significant cardiac disease, significant anemia, pregnancy, and men whose female partner is pregnant or plans to become pregnant

[3]Recommended regimen based on genotype, prior treatment, presence comorbidities (e.g., HIV or post-transplant) should use VA Hepatitis C Treatment considerations (*Hepatitis C Treatment Considerations - Viral Hepatitis and Liver Disease (va.gov)* or IDSA/AASLD Guidelines (https://www.hcvguidelines.org)

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