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Hepatitis C Direct Acting Antivirals Prior Authorization

Drug(s) Applied:	**MAVYRET** (glecaprevir/pibrentasvir) **Sofosbuvir-Velpatasvir**

Criteria:

Drug(s) Applied will be approved when the requested medication is being used for an FDA approved indication and all of the following criteria are met:

I. Initial Approval Criteria
   A. **Hepatitis C** as indicated by chart notes within past 120 days
      1. Hepatitis C is 1, 2, 3, 4, 5, 6 or unknown genotype **and**
      2. Patient has been screened for current or prior hepatitis B viral (HBV) infection and ONE of the following applies:
         a) Prescriber has provided information indicating the patient tested negative for HBV **or**
         b) Prescriber has provided information indicating the patient tested positive for current or prior HBV infection, with documentation that the patient will be monitored for HBV reactivation (flare-ups) during and after treatment with the requested agent **and**
      3. Patient's treatment history includes ONE of the following:
         a) Patient is hepatitis C treatment naïve **or**
         b) Patient has had ONE of the following treatments prior to taking the requested drug:
            (1) NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir) but without prior treatment with an NS3/4A protease inhibitor (PI) **or**
            (2) NS3/4A protease inhibitor (e.g., simeprevir, boceprevir, telaprevir) but without prior treatment with an NS5A inhibitor **or**
            (3) Prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor **and**
      4. If the requested agent is Sofosbuvir-Velpatasvir, then the following applies:
         a) Patient weighs ≥30 kg **and**
         b) Patient has been assessed for liver cirrhosis and ONE of the following applies:
            (1) Patient does not have decompensated liver disease **or**
            (2) Patient does have decompensated liver disease and will be using the requested agent in combination with ribavirin **and**

5. If the requested agent is Mayvret then the following applies:
    a) Patient's age is 12 years or older **and**
    b) Prescriber has provided documentation supporting the use of the requested agent if it is being prescribed in the context of **one** of the following:
        (1) Patient has HIV-1 infection **or**
        (2) Patient is pregnant, plans to become pregnant or is breastfeeding **or**
        (3) Patient had a liver or kidney transplant **and**
    c) Patient is NOT taking the requested agent with another direct acting antiviral agent, atazanavir or rifampin **and**
    d) Patient does NOT have moderate or severe hepatic impairment (Child-Pugh B or C) or any history of prior hepatic decompensation **and**
    e) Patient has been assessed for liver cirrhosis and ONE of the following applies:
        (1) Prescriber notes that the patient does not have cirrhosis and is qualified for simplified treatment and ALL of the following applies:
            (a) NOT currently pregnant **and**
            (b) No known or suspected hepatocellular carcinoma **or**

        (2) Patient does have compensated cirrhosis and is qualified for simplified treatment & **ALL** of the following applies:
            (a) Patient has a Child-Turcotte-Pugh (CTP) score $\leq$ 7 (ascites, hepatic encephalopathy, total bilirubin greater than 2.0 mg/dL, albumin less than or equal to 3.5 g/dL, or INR greater than or equal to 1.7) **and**
            (b) Does NOT have end-stage renal disease (i.e., eGFR less than 30 mL/min/m^2) **and**
            (c) NOT currently pregnant **and**
            (d) No known or suspected hepatocellular carcinoma **and**
6. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g.,hepatology, or infectious disease)

Approval Duration: For Sofosbuvir-Velpatasvir 12 weeks; for Mayvret as indicated in the below Table

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Table: Mavyret Treatment Recommendations based on FDA labeling

Genotype	Patient Factors - adults and pediatric patients 3 years of age and older*+	Duration	
		No Cirrhosis	Compensated Cirrhosis
1, 2, 3, 4, 5, or 6	Liver or kidney transplant recipients	12 weeks	12 weeks
1	Liver or kidney transplant recipients who are treatment experienced with an NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir) but without prior treatment with an NS3/4A protease inhibitor (PI)	16 weeks	16 weeks
3	Liver or kidney transplant recipients who are treatment experienced with PRS (i.e., Prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor)	16 weeks	16 weeks
1, 2, 3, 4, 5, or 6	Treatment naïve	8 weeks	8 weeks
1	Treatment experienced with an NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir) but without prior treatment with an NS3/4A protease inhibitor (PI)	16 weeks	16 weeks
1	Treatment experienced with an NS3/4A protease inhibitor (e.g., simeprevir, boceprevir, telaprevir) but without prior treatment with an NS5A inhibitor	12 weeks	12 weeks
1, 2, 4, 5, or 6	Treatment experienced with PRS (i.e., Prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor)	8 weeks	12 weeks
3	Treatment experienced with PRS (i.e., Prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor)	16 weeks	16 weeks

*HCV/HIV-1 co-infection, follow recommendations in the table above
+ Patients with any degree of kidney impairment (including those on hemodialysis), follow recommendations in the table above
Policy Owned by: Curative PBM team