Pharmacy Policy Bulletin: J-0140 Hepatitis C Oral Agents – Commercial and Healthcare Reform	
Number: J-0140	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Quantity Limits (1., 2., 3., or 4.):** **1.** Rx Mgmt Quantity Limits = Safety/Specialty **2.** Rx Mgmt Quantity Limits = Safety/Specialty + Dose Opt **3.** Rx Mgmt Quantity Limits = Safety/Specialty + Dose Opt + Watchful **4.** Rx Mgmt Performance = MRXC = Yes **Healthcare Reform**: Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** Excluding plans with the Commercial National Select or Commercial Core formulary
Version: J-0140-041	**Original Date:** 11/01/2011
Effective Date: 10/08/2025	**Review Date:** 09/17/2025

Drugs Product(s):	• Epclusa (sofosbuvir/velpatasvir) – *brand and authorized generic* • Harvoni (ledipasvir/sofosbuvir) – *brand and authorized generic* • Mavyret (glecaprevir/pibrentasvir) • Sovaldi (sofosbuvir) • Viekira Pak (ombitasvir/paritaprevir/ritonavir/dasabuvir) • Vosevi (sofosbuvir/velpatasvir/voxilaprevir) • Zepatier (elbasvir/grazoprevir)
FDA-Approved Indication(s):	• Epclusa (sofosbuvir/velpatasvir) is indicated for the treatment adults and pediatric patients 3 years of age and older with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis or with decompensated cirrhosis for use in combination with ribavirin. • Harvoni (ledipasvir/sofosbuvir) is indicated for the treatment of chronic HCV in adults and pediatric patients 3 years of age and older for genotype 1, 4, 5, and 6 infection without cirrhosis or with compensated cirrhosis, genotype 1 infection with decompensated cirrhosis in combination with ribavirin, genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis in combination with ribavirin. • Mavyret (glecaprevir/pibrentasvir) is indicated for treatment of adult and pediatric patients 3 years of age and older with acute or chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis or in patients with genotype 1 infection who previously have been treated with an NS5A inhibitor or NS3/4A protease inhibitor (but not both). • Sovaldi (sofosbuvir) is indicated for the treatment of chronic HCV infection as a component of a combination antiviral treatment regimen. Efficacy has been

	established in subjects with HCV genotype 1, 2, 3, or 4 infection, without cirrhosis or with compensated cirrhosis. Sovaldi is also indicated in combination with ribavirin for treatment of chronic HCV infection genotypes 2 or 3 in patients ages 3 to 17 years old. • Viekira Pak (dasabuvir/ombitasvir/paritaprevir/ritonavir) is indicated for the treatment of adult patients with chronic HCV genotype 1a without cirrhosis or with compensated cirrhosis for use in combination with ribavirin and genotype 1b without cirrhosis or with compensated cirrhosis. The AASLD guidelines for testing, managing and treating hepatitis C no longer include the Viekira Pak as a treatment regimen for hepatitis C infection. • Vosevi (sofosbuvir/velpatasvir/voxilaprevir) is indicated for treatment of adults without cirrhosis or with compensated cirrhosis and chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection who have previously been treated with an HCV regimen containing an NS5A inhibitor or genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor. • Zepatier (elbasvir/grazoprevir) is indicated for the treatment of chronic HCV genotype 1 or 4 infection in adult and pediatric patients 12 years of age and older weighing at least 30 kg. It is also indicated for use with ribavirin in certain patient populations.

Background:	• Hepatitis C is a single stranded RNA blood-borne virus. Infection usually occurs via percutaneous exposure and once the virus enters the host, it predominantly infects the liver and replicates in hepatocytes. As a result, 75-85% of infections progress to chronic infection, and 20-25% progress to cirrhosis over 20 years. An estimated 2.4 million people in the United States are living with HCV infection. The majority of infected individuals may not be aware of the infection due to lack of clinical signs and symptoms. • Per the American Association for the Study of Liver diseases and Infectious Diseases Society of America Hepatitis C Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C, after the initial diagnosis of acute HCV with viremia, HCV treatment should be initiated without awaiting spontaneous resolution. Owing to high efficacy and safety, the same regimens that are recommended for chronic HCV infection are recommended for acute infection. • Epclusa: Velpatasvir is an inhibitor of the HCV NS5A protein, which is required for viral replication. Sofosbuvir is an inhibitor of the HCV NS5B RNA-dependent RNA polymerase, which is required for viral replication. Both are direct-acting antivirals (DAAs) against HCV. • Harvoni: Ledipasvir is an inhibitor of the HCV NS5A protein, which is required for viral replication. Sofosbuvir is an inhibitor of the HCV NS5B RNA-dependent RNA polymerase, which is required for viral replication. Both are DAAs against HCV. • Mavyret: Glecaprevir is an inhibitor of the HCV NS3/4A protease which is essential for viral replication. Pibrentasvir is an inhibitor of the HCV NS5A protein, which is required for viral replication. • Sovaldi: Sofosbuvir is an inhibitor of the HCV NS5B RNA-dependent RNA polymerase, which is required for viral replication. It is a DAAs against HCV. • Viekira Pak: Paritaprevir is an NS3/4A protease inhibitor that is co-dosed with ritonavir, a CYP3A4 inhibitor, to significantly increase ABT-450's peak and trough concentrations, enabling once daily dosing. Ombitasvir is an HCV NS5A inhibitor and dasabuvir is an HCV NS5B inhibitor. All three drugs (excluding ritonavir) are DAAs that interfere with the enzymes needed by HCV to multiply. • Vosevi: Voxilaprevir is an inhibitor of the HCV NS3/4A protease which is essential for viral replication. Velpatasvir is an inhibitor of the HCV NS5A protein, which is required for viral replication. Sofosbuvir is an inhibitor of the HCV NS5B RNA-dependent RNA polymerase, which is required for viral replication. All are DAAs against HCV.

- Zepatier: Elbasvir is an NS5A inhibitor and grazoprevir is an NS3/4A protease inhibitor. Both are essential for viral replication. Both are DAAs against HCV.

Targets for DAAs are as follows:

NS3/4A Protease Inhibitors	NS5A inhibitors	NS5B inhibitors
• Glecaprevir • Grazoprevir • Paritaprevir • Simeprevir • Voxilaprevir	• Daclatasvir • Elbasvir • Ledipasvir • Ombitasvir • Pibrentasvir • Velpatasvir	• Dasabuvir • Sofosbuvir

Member treatment terminology is as follows:

Treatment Term	Definition
Treatment-naïve	Patients who have not been previously treated with interferon, peginterferon, ribavirin, or any HCV DAA agent
Relapser	Patients who had an undetectable HCV RNA level at the end of prior therapy, but had a subsequent detectable HCV RNA level during the follow-up period
Partial responder	Patients who had an HCV RNA reduction of ≥ 2 $\log_{10}$ after 12 weeks of prior therapy, but still had a detectable HCV RNA level during the treatment period.
Null responder or non-responder	Patients who had an HCV RNA that did not drop by at least 2 $\log_{10}$ during treatment.

METAVIR score is defined as follows:

Stage	Definition	Explanation
F0	No fibrosis	No scarring
F1	Portal fibrosis without septa	Minimal scarring
F2	Few septa	Scarring has occurred and extends outside the areas in the liver that contains blood vessels
F3	Numerous septa without cirrhosis	Bridging fibrosis is spreading and connecting to other areas that contain fibrosis.
F4	Cirrhosis	Advanced scarring of the liver

Types of Cirrhosis are defined as follows:

Child-Pugh A	Mild Hepatic Impairment	Compensated Cirrhosis
Child-Pugh B	Moderate Hepatic Impairment	Decompensated Cirrhosis
Child-Pugh C	Severe Hepatic Impairment	

- Prescribing Considerations:
  - Acute HCV infection is defined as presenting within 6 months of the exposure. During this period, there is a 20 – 50% chance of spontaneous resolution of the infection.
  - Chronic infection (6 months or greater from exposure) is diagnosed via a positive test for antibodies to HCV (anti-HCV) and a HCV detection test (nucleic acid test for HCV RNA or test for HCV antigens).
  - Organs from HCV-viremic donors may be considered for use in recipients without HCV infection. Use of these organs increases the pool of available

	organs, patient access to transplantation, and potentially reduces waitlist time and mortality. When considering use of DAA agents for HCV prophylaxis in patients without HCV infection, the overall number of published cases is small and treatment approaches vary. Known reported risks include DAA treatment failure with emergence of complex resistance-associated substitutions (RASs). Due to the limited and heterogeneous experience and lack of longer-term safety data, strong consideration should be given to performing these transplantations and receiving DAA treatment under institutional review board (IRB)-approved protocols as recommended by the American Society of Transplantation consensus panel. HCV infection in patients after transplantation mirrors normal HCV disease progression with an acute phase in all patients followed by an approximate 75% progression to chronic HCV. o First generation protease inhibitors include: boceprevir and telaprevir. o The member should not be using Sovaldi as monotherapy. The only product currently available for combination with Sovaldi is Zepatier. o DAAs should not be used in combination. o According to the AASLD guidelines, most patients with decompensated cirrhosis experience improvement in clinical and biochemical indicators of liver disease when treated with direct-acting antivirals. Signs and symptoms of decompensated cirrhosis include bleeding varices, ascites, encephalopathy, and jaundice. o The AASLD guidelines no longer contain retreatment recommendations for interferon or interferon plus first generation protease inhibitor failures because the cure rates with modern DAA regimens in these populations were comparable to treatment naive patients. o Ribavirin should not be used in patients with a creatinine clearance less than 50 ml/min. o The prescribing clinician is a gastroenterologist, hepatologist, infectious diseases physician, or a transplantation physician. o According to AASLD guidelines, patients with HCV/HIV require intense monitoring in order to recognize and manage potential interactions with antiretroviral medications.

Approval Criteria

Members who are established on an FDA-approved regimen from another prescription drug plan or Highmark plan without prior authorization restrictions will be allowed to continue therapy as outlined in the 'Duration of Authorization' section of this policy. Members established on samples or by paying out-of-pocket for direct-acting antivirals will only be granted a continuation of therapy if the criteria within this policy is met.

a. Approval Criteria

A. Treatment Naïve Adult

When a benefit, coverage of HCV antiviral therapy may be approved when all of the following criteria are met **(1. through 11.)**:

1. The member is 18 years of age or older.

2. The member meets one (1) of the following criteria **(a. or b.)**:

- **a.** The member has a diagnosis of chronic HCV. (ICD-10: B18.2)
- **b.** If the request is for Mavyret, the member has a diagnosis of acute (ICD-10: B17) or chronic HCV (ICD-10: B18.2).

3. The member has not received prior HCV treatment.

4. The prescriber provides all the following information **(a. and b.)**:

- **a.** The member's cirrhosis status

b. The member's liver transplant history

5. The member is prescribed an appropriate regimen based on patient characteristics per the FDA-approved labeling and/or AASLD/IDSA guidelines (see table 1. below).
6. The prescriber attests the member or parent/guardian has been educated on the potential adverse effects of alcohol or intravenous (IV) drug abuse, including the risk of misuse, abuse, and addiction.
7. If the member meets one (1) of the following diagnoses, the prescriber provides attestation that an offer of a referral for substance abuse disorder treatment and care management was made **(a., b., or c.)**:
   - **a.** The member has alcohol use disorder.
   - **b.** The member is an IV drug abuser.
   - **c.** The member has a history of substance abuse within the past 6 months.
8. The member has had appropriate resistance-associated substitutions (RASs) testing performed, based upon agent and genotype (if applicable per table 1. below).
9. If the request is for Harvoni and the member is genotype 1a or 1b, the appropriate duration has been evaluated based upon the following criteria **(a. or b.)**:
   - **a.** If the request is for 12 weeks of therapy, the member meets one (1) of the following **(i. through v.):**
     - **i.** The member's HCV RNA $\geq$ 6 million IU/mL.
     - **ii.** The member is HIV-infected.
     - **iii.** The member has cirrhosis.
     - **iv.** The member had a prior liver transplant.
     - **v.** The prescriber attests that 8 weeks of therapy would be inappropriate.
   - **b.** If the request is for 8 weeks of therapy the member meets all of the following criteria **(i., ii., and iii.)**
     - **i.** The member is HIV-uninfected.
     - **ii.** The member's HCV RNA < 6 million IU/mL
     - **iii.** The member does not have cirrhosis
10. If the request is for Mavyret for 12 weeks of therapy, the member meets one (1) of the following criteria **(a. or b.)**:
    - **a.** The member is HIV/HCV co-infected
    - **b.** The member had a prior liver transplant.
11. If the request is for a non-preferred product, the member has a contraindication or is otherwise not a candidate for all preferred regimens (see table 1. below).

Table 1. Treatment-Naïve Adults

HCV Genotype	Prior Liver Transplant	Cirrhosis Status	Recommended Medication and Duration	
			Preferred Products	Non-Preferred Products
1a	No	No Cirrhosis	Mavyret x 8 weeks Harvoni x 8 weeks (HCV RNA <6 million IU/mL and HIV uninfected) Harvoni x 12 weeks Epclusa x 12 weeks	Zepatier x 12 weeks
		Compensated	Harvoni x 12 weeks Epclusa x 12 weeks Mavyret x 8 weeks	Zepatier x 12 weeks
		Decompensated	Harvoni + ribavirin x 12 weeks Epclusa x ribavirin x 12 weeks Harvoni x 24 weeks Epclusa x 24 weeks	
	Yes	No Cirrhosis	Mavyret x 12 weeks Harvoni x 12 weeks	

			Epclusa x 12 weeks	
		Compensated	Harvoni x 12 weeks Epclusa x 12 weeks Mavyret x 12 weeks	
		Decompensated	Harvoni + ribavirin x 12 weeks Epclusa + ribavirin x 12 weeks	
1b	No	No Cirrhosis	Mavyret x 8 weeks Harvoni x 8 weeks (HCV RNA <6 million IU/mL and HIV uninfected) Harvoni x 12 weeks Epclusa x 12 weeks Zepatier x 12 weeks	
		Compensated	Harvoni x 12 weeks Epclusa x 12 weeks Mavyret x 8 weeks Zepatier x 12 weeks	
		Decompensated	Harvoni + ribavirin x 12 weeks Epclusa x ribavirin x 12 weeks Harvoni x 24 weeks Epclusa x 24 weeks	
	Yes	No Cirrhosis	Mavyret x 12 weeks Harvoni x 12 weeks Epclusa x 12 weeks	
		Compensated	Harvoni x 12 weeks Epclusa x 12 weeks Mavyret x 12 weeks	
		Decompensated	Harvoni + ribavirin x 12 weeks Epclusa + ribavirin x 12 weeks	
2	No	No Cirrhosis	Mavyret x 8 weeks Epclusa x 12 weeks	
		Compensated	Mavyret x 8 weeks Epclusa x 12 weeks	
		Decompensated	Epclusa + ribavirin x 12 weeks Epclusa x 24 weeks	
	Yes	No Cirrhosis	Mavyret x 12 weeks Epclusa x 12 weeks	
		Compensated	Mavyret x 12 weeks Epclusa x 12 weeks	
		Decompensated	Epclusa + ribavirin x 12 weeks	
3	No	No Cirrhosis	Mavyret x 8 weeks Epclusa x 12 weeks	
		Compensated	Mavyret x 8 weeks Epclusa x 12 weeks for patients without baseline NS5A RAS	Vosevi x 12 weeks for patients with baseline NS5A RAS Y93H for velpatasvir

			Y93H for velpatasvir	Epclusa + ribavirin x 12 weeks for patients with baseline NS5A Y93H for velpatasvir
		Decompensated	Epclusa + ribavirin x 12 weeks Epclusa x 24 weeks	
	Yes	No Cirrhosis	Mavyret x 12 weeks Epclusa x 12 weeks	
		Compensated	Mavyret x 12 weeks Epclusa x 12 weeks	
		Decompensated	Epclusa + ribavirin x 12 weeks	
4	No	No Cirrhosis	Mavyret x 8 weeks Harvoni x 12 weeks Epclusa x 12 weeks Zepatier x 12 weeks	
		Compensated	Epclusa x 12 weeks Mavyret x 8 weeks Harvoni x 12 weeks Zepatier x 12 weeks	
		Decompensated	Harvoni + ribavirin x 12 weeks Epclusa x ribavirin x 12 weeks Harvoni x 24 weeks Epclusa x 24 weeks	
	Yes	No Cirrhosis	Mavyret x 12 weeks Harvoni x 12 weeks Epclusa x 12 weeks	
		Compensated	Harvoni x 12 weeks Epclusa x 12 weeks Mavyret x 12 weeks	
		Decompensated	Harvoni + ribavirin x 12 weeks Epclusa + ribavirin x 12 weeks	
5	No	No Cirrhosis	Mavyret x 8 weeks Epclusa x 12 weeks Harvoni x 12 weeks	
		Compensated		
		Decompensated	Harvoni + ribavirin x 12 weeks Epclusa x ribavirin x 12 weeks Harvoni x 24 weeks Epclusa x 24 weeks	
	Yes	No Cirrhosis	Mavyret x 12 weeks Harvoni x 12 weeks Epclusa x 12 weeks	
		Compensated	Harvoni x 12 weeks Epclusa x 12 weeks Mavyret x 12 weeks	
		Decompensated	Harvoni + ribavirin x 12 weeks Epclusa + ribavirin x 12	

			weeks	
6	No	No Cirrhosis	Mavyret x 8 weeks Epclusa x 12 weeks Harvoni x 12 weeks	
		Compensated		
		Decompensated	Harvoni + ribavirin x 12 weeks Epclusa x ribavirin x 12 weeks Harvoni x 24 weeks Epclusa x 24 weeks	
	Yes	No Cirrhosis	Mavyret x 12 weeks Harvoni x 12 weeks Epclusa x 12 weeks	
		Compensated	Harvoni x 12 weeks Epclusa x 12 weeks Mavyret x 12 weeks	
		Decompensated	Harvoni + ribavirin x 12 weeks Epclusa + ribavirin x 12 weeks	

*Note: Brand names of medications are used for simplification; prior authorization criteria refer to **brands and any generic formulations (including authorized generics)** available.*

B. <u>Treatment Experienced Adults</u>

When a benefit, coverage of HCV antiviral therapy may be approved when all of the following criteria are met **(1. through 9.)**:

1. The member is 18 years of age or older.
2. The member has a diagnosis of chronic HCV. (ICD-10: B18.2)
3. The prescriber documents any previous therapies the member has used for chronic HCV with reason for discontinuation and/or failure.
4. The prescriber provides all the following information **(a. and b.)**:
  a. The member's cirrhosis status
  b. The member's liver transplant history
5. The member is prescribed an appropriate regimen based on patient characteristics per the FDA-approved labeling and/or AASLD/IDSA guidelines (see table 2. below).
6. The prescriber attests the member or parent/guardian has been educated on the potential adverse effects of alcohol or intravenous (IV) drug abuse, including the risk of misuse, abuse, and addiction.
7. If the member meets one (1) of the following diagnoses, the prescriber provides attestation that an offer of a referral for substance abuse disorder treatment and care management was made **(a., b., or c.)**:
  a. The member has alcohol use disorder.
  b. The member is an IV drug abuser.
  c. The member has a history of substance abuse within the past 6 months.
8. The member has had appropriate resistance-associated substitutions (RASs) testing performed, based upon agent and genotype (if applicable see table 2. below).
9. If the request is for a non-preferred product, the member has a contraindication or is otherwise not a candidate for all preferred regimens (see table 2. below).

Table 2. Treatment Experienced Adults*					
HCV Genotype	Prior Liver Trans-plant	Cirrhosis Status	Prior Treatment	Recommended Medication and Duration	
				Preferred Products	Non-Preferred Products
1a	No	No	Sofosbuvir/ribavirin ±		

		Cirrhosis	interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir	Vosevi x 12 weeks	Mavyret x 16 weeks
			Elbasvir/grazoprevir	Vosevi x 12 weeks	
			Glecaprevir/pibrentasvir	Mavyret + sofosobuvir + ribavirin x 16 weeks Vosevi x 12 weeks	
			Sofosbuvir/Velpatasvir/ Voxilaprevir	Mavyret + sofosobuvir + ribavirin x 16 weeks Vosevi + ribavirin x 24 weeks	
			Sofosbuvir + glecaprevir/pibrentasvir	Mavyret + sofosobuvir + ribavirin x 24 weeks Vosevi + ribavirin x 24 weeks	
		Compensated	Sofosbuvir/ribavirin ± interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir	Vosevi x 12 weeks	Mavyret x 16 weeks
			Elbasvir/grazoprevir	Vosevi x 12 weeks	
			Glecaprevir/pibrentasvir	Mavyret + sofosobuvir + ribavirin x 16 weeks Vosevi + ribavirin x 12 weeks	
			Sofosbuvir/Velpatasvir/ Voxilaprevir	Mavyret + sofosobuvir + ribavirin x 16 weeks Vosevi + ribavirin x 24 weeks	
			Sofosbuvir + glecaprevir/pibrentasvir	Mavyret + sofosobuvir + ribavirin x 24 weeks Vosevi + ribavirin x 24 weeks	
		Decompensated	Sofosbuvir	Harvoni + ribavirin x 24 weeks	

				Epclusa + ribavirin x 24 weeks	
			NS5A inhibitor	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	
	Yes	No Cirrhosis	Interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon	Mavyret x 12 weeks Harvoni x 12 weeks Epclusa x 12 weeks	
			DAA-Experienced	Vosevi x 12 weeks	
		Compensated	Interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon	Harvoni x 12 weeks Epclusa x 12 weeks Mavyret x 12 weeks	
			DAA-Experienced	Vosevi ± ribavirin x 12 weeks	
		Decompensated	All Treatment-Experienced Patients	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	
1b	No	No Cirrhosis	Sofosbuvir/ribavirin ± interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir	Vosevi x 12 weeks	Mavyret x 16 weeks
			Elbasvir/grazoprevir	Vosevi x 12 weeks	
			Glecaprevir/ pibrentasvir	Mavyret + sofosobuvir + ribavirin x 16 weeks Vosevi x 12 weeks	
			Sofosbuvir/Velpatasvir/ Voxilaprevir	Mavyret + sofosobuvir + ribavirin x 16 weeks Vosevi + ribavirin x 24 weeks	
			Sofosbuvir + glecaprevir/pibrentasvir	Mavyret + sofosbuvir + ribavirin x 24 weeks	

				Vosevi + ribavirin x 24 weeks	
		Compensated	Sofosbuvir/ribavirin ± interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir	Vosevi x 12 weeks	Mavyret x 16 weeks
			Elbasvir/grazoprevir	Vosevi x 12 weeks	
			Glecaprevir/pibrentasvir	Mavyret + sofosobuvir + ribavirin x 16 weeks Vosevi + ribavirin x 12 weeks	
			Sofosbuvir/Velpatasvir/ Voxilaprevir	Mavyret + sofosobuvir + ribavirin x 16 weeks Vosevi + ribavirin x 24 weeks	
			Sofosbuvir + glecaprevir/pibrentasvir	Mavyret + sofosobuvir + ribavirin x 24 weeks Vosevi + ribavirin x 24 weeks	
		Decompensated	Sofosbuvir	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	
			NS5A inhibitor	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	
	Yes	No Cirrhosis	Interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon	Mavyret x 12 weeks Harvoni x 12 weeks Epclusa x 12 weeks	
			DAA-Experienced	Vosevi x 12 weeks	
		Compensated	Interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon	Harvoni x 12 weeks Epclusa x 12 weeks Mavyret x 12	

				weeks	
			DAA-Experienced	Vosevi ± ribavirin x 12 weeks	
		Decompensated	All Treatment-Experienced Patients	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	
2	No	No Cirrhosis	Sofosbuvir/ribavirin ± interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir	Vosevi x 12 weeks	Mavyret x 16 weeks
			Elbasvir/grazoprevir	Vosevi x 12 weeks	
			Glecaprevir/ pibrentasvir	Mavyret + sofosobuvir + ribavirin x 16 weeks Vosevi x 12 weeks	
			Sofosbuvir/Velpatasvir/ Voxilaprevir	Mavyret + sofosobuvir + ribavirin x 16 weeks Vosevi + ribavirin x 24 weeks	
			Sofosbuvir + glecaprevir/pibrentasvir	Mavyret + sofosobuvir + ribavirin x 24 weeks Vosevi + ribavirin x 24 weeks	
		Compensated	Sofosbuvir/ribavirin ± interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir	Vosevi x 12 weeks	Mavyret x 16 weeks
			Elbasvir/grazoprevir	Vosevi x 12 weeks	
			Glecaprevir/pibrentasvir	Mavyret + sofosobuvir + ribavirin x 16 weeks Vosevi + ribavirin x 12 weeks	
			Sofosbuvir/Velpatasvir/ Voxilaprevir	Mavyret + sofosobuvir + ribavirin x 16 weeks Vosevi + ribavirin x 24	

				weeks	
			Sofosbuvir + glecaprevir/pibrentasvir	Mavyret + sofosobuvir + ribavirin x 24 weeks Vosevi + ribavirin x 24 weeks	
		Decompensated	Sofosbuvir	Epclusa + ribavirin x 24 weeks	
			NS5A inhibitor	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	
	Yes	No Cirrhosis	Interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon	Mavyret x 12 weeks Epclusa x 12 weeks	
			DAA-Experienced	Vosevi x 12 weeks	
		Compensated	Interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon	Epclusa x 12 weeks Mavyret x 12 weeks	
			DAA-Experienced	Vosevi ± ribavirin x 12 weeks	
		Decompensated	All Treatment-Experienced Patients	Epclusa + ribavirin x 24 weeks	
3	No	No Cirrhosis	Sofosbuvir/ribavirin ± interferon	Vosevi x 12 weeks	Mavyret x 16 weeks
			Sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir	Vosevi x 12 weeks	
			Elbasvir/grazoprevir	Vosevi x 12 weeks	
			Glecaprevir/pibrentasvir	Mavyret + sofosobuvir + ribavirin x 16 weeks Vosevi x 12 weeks	
			Sofosbuvir/Velpatasvir/ Voxilaprevir	Mavyret + sofosobuvir + ribavirin x 16 weeks Vosevi + ribavirin x 24 weeks	
			Sofosbuvir + glecaprevir/pibrentasvir	Mavyret + sofosobuvir + ribavirin x 24	

				weeks Vosevi + ribavirin x 24 weeks	
		Compensated	Sofosbuvir/ribavirin ± interferon	Vosevi + ribavirin x 12 weeks	Mavyret x 16 weeks
			Sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir	Vosevi + ribavirin x 12 weeks	
			Elbasvir/grazoprevir	Vosevi + ribavirin x 12 weeks	
			Glecaprevir/ pibrentasvir	Mavyret + sofosobuvir + ribavirin x 16 weeks Vosevi + ribavirin x 12 weeks	
			Sofosbuvir/Velpatasvir/ Voxilaprevir, sofosbuvir + glecaprevir/pibrentasvir	Mavyret + sofosobuvir + ribavirin x 24 weeks Vosevi + ribavirin x 24 weeks	
		Decompensated	Sofosbuvir	Epclusa + ribavirin x 24 weeks	
			NS5A inhibitor	Epclusa + ribavirin x 24 weeks	
	Yes	No Cirrhosis	Interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon	Mavyret x 12 weeks Epclusa x 12 weeks	
			DAA-Experienced	Vosevi x 12 weeks	
		Compensated	Interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon	Epclusa x 12 weeks Mavyret x 12 weeks	
			DAA-Experienced	Vosevi ± ribavirin x 12 weeks	
		Decompensated	All Treatment-Experienced Patients	Epclusa + ribavirin x 24 weeks	
4	No	No Cirrhosis	Sofosbuvir/ribavirin ± interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir	Vosevi x 12 weeks	Mavyret x 16 weeks
			Elbasvir/grazoprevir	Vosevi x 12 weeks	

			Glecaprevir/pibrentasvir	Mavyret + sofosobuvir + ribavirin x 16 weeks Vosevi x 12 weeks	
			Sofosbuvir/Velpatasvir/ Voxilaprevir	Mavyret + sofosobuvir + ribavirin x 16 weeks Vosevi + ribavirin x 24 weeks	
			Sofosbuvir + glecaprevir/pibrentasvir	Mavyret + sofosobuvir + ribavirin x 24 weeks Vosevi + ribavirin x 24 weeks	
		Compensated	Sofosbuvir/ribavirin ± interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir	Vosevi x 12 weeks	Mavyret x 16 weeks
			Elbasvir/grazoprevir	Vosevi x 12 weeks	
			Glecaprevir/ pibrentasvir	Mavyret + sofosobuvir + ribavirin x 16 weeks Vosevi + ribavirin x 12 weeks	
			Sofosbuvir/Velpatasvir/ Voxilaprevir	Mavyret + sofosobuvir + ribavirin x 16 weeks Vosevi + ribavirin x 24 weeks	
			Sofosbuvir + glecaprevir/pibrentasvir	Mavyret + sofosobuvir + ribavirin x 24 weeks Vosevi + ribavirin x 24 weeks	
		Decompensated	Sofosbuvir	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	
			NS5A inhibitor	Harvoni + ribavirin x 24	

				weeks Epclusa + ribavirin x 24 weeks	
	Yes	No Cirrhosis	Interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon	Mavyret x 12 weeks Harvoni x 12 weeks Epclusa x 12 weeks	
			DAA-Experienced	Vosevi x 12 weeks	
		Compensated	Interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon	Harvoni x 12 weeks Epclusa x 12 weeks Mavyret x 12 weeks	
			DAA-Experienced	Vosevi ± ribavirin x 12 weeks	
		Decompensated	All Treatment-Experienced Patients	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	
5	No	No Cirrhosis	Sofosbuvir/ribavirin ± interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir	Vosevi x 12 weeks	Mavyret x 16 weeks
			Elbasvir/grazoprevir	Vosevi x 12 weeks	
			Glecaprevir/ pibrentasvir	Mavyret + sofosobuvir + ribavirin x 16 weeks Vosevi x 12 weeks	
			Sofosbuvir/Velpatasvir/ Voxilaprevir	Mavyret + sofosobuvir + ribavirin x 16 weeks Vosevi + ribavirin x 24 weeks	
			Sofosbuvir + glecaprevir/pibrentasvir	Mavyret + sofosobuvir + ribavirin x 24 weeks Vosevi + ribavirin x 24 weeks	

		Compensated	Sofosbuvir/ribavirin ± interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir	Vosevi x 12 weeks	Mavyret x 16 weeks
			Elbasvir/grazoprevir	Vosevi x 12 weeks	
			Glecaprevir/ pibrentasvir	Mavyret + sofosobuvir + ribavirin x 16 weeks Vosevi + ribavirin x 12 weeks	
			Sofosbuvir/Velpatasvir/ Voxilaprevir	Mavyret + sofosobuvir + ribavirin x 16 weeks Vosevi + ribavirin x 24 weeks	
			Sofosbuvir + glecaprevir/pibrentasvir	Mavyret + sofosobuvir + ribavirin x 24 weeks Vosevi + ribavirin x 24 weeks	
		Decompensated	Sofosbuvir	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	
			NS5A inhibitor	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	
	Yes	No Cirrhosis	Interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon	Mavyret x 12 weeks Harvoni x 12 weeks Epclusa x 12 weeks	
			DAA-Experienced	Vosevi x 12 weeks	
		Compensated	Interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon	Harvoni x 12 weeks Epclusa x 12 weeks Mavyret x 12 weeks	
			DAA-Experienced	Vosevi ± ribavirin x 12	

				weeks	
		Decompensated	All Treatment-Experienced Patients	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	
6	No	No Cirrhosis	Sofosbuvir/ribavirin ± interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir	Vosevi x 12 weeks	Mavyret x 16 weeks
			Elbasvir/grazoprevir	Vosevi x 12 weeks	
			Glecaprevir/ pibrentasvir	Mavyret + sofosobuvir + ribavirin x 16 weeks Vosevi x 12 weeks	
			Sofosbuvir/Velpatasvir/ Voxilaprevir	Mavyret + sofosbuvir + ribavirin x 16 weeks Vosevi + ribavirin x 24 weeks	
			Sofosbuvir + glecaprevir/pibrentasvir	Mavyret + sofosbuvir + ribavirin x 24 weeks Vosevi + ribavirin x 24 weeks	
		Compensated	Sofosbuvir/ribavirin ± interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir	Vosevi x 12 weeks	Mavyret x 16 weeks
			Elbasvir/grazoprevir	Vosevi x 12 weeks	
			Glecaprevir/ pibrentasvir	Mavyret + sofosobuvir + ribavirin x 16 weeks Vosevi + ribavirin x 12 weeks	
			Sofosbuvir/Velpatasvir/ Voxilaprevir	Mavyret + sofosobuvir + ribavirin x 16 weeks Vosevi + ribavirin x 24 weeks	
			Sofosbuvir + glecaprevir/pibrentasvir	Mavyret + sofosobuvir +	

				ribavirin x 16 weeks Vosevi + ribavirin x 24 weeks	
		Decompensated	Sofosbuvir	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	
			NS5A inhibitor	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	
	Yes	No Cirrhosis	Interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon	Mavyret x 12 weeks Harvoni x 12 weeks Epclusa x 12 weeks	
			DAA-Experienced	Vosevi x 12 weeks	
		Compensated	Interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon	Harvoni x 12 weeks Epclusa x 12 weeks Mavyret x 12 weeks	
			DAA-Experienced	Vosevi ± ribavirin x 12 weeks	
		Decompensated	All Treatment-Experienced Patients	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	

*Note: Brand names of medications are used for simplification; prior authorization criteria refer to **brands and any generic formulations (including authorized generics)** available.*
**The AASLD guidelines no longer contain retreatment recommendations for interferon or interferon plus first generation protease inhibitor failures because the cure rates with modern DAA regimens in these populations were comparable to treatment naive patients.*

C. Treatment Naïve Pediatrics

When a benefit, coverage of HCV antiviral therapy may be approved when all of the following criteria are met **(1. through 9.)**:

1. The member is between 3 and 17 years of age.
2. The member meets one (1) of the following criteria **(a. or b.)**:
  a. The member has a diagnosis of chronic HCV. (ICD-10: B18.2)
  b. If the request is for Mavyret, the member has a diagnosis of acute (ICD-10: B17) or chronic HCV (ICD-10: B18.2).
3. The member has not received prior HCV treatment.
4. The prescriber provides the member's cirrhosis status.

5. The member is prescribed an appropriate regimen based on patient characteristics per the FDA-approved labeling and/or AASLD/IDSA guidelines (see table 3. below).
6. The prescriber attests the member or parent/guardian has been educated on the potential adverse effects of alcohol or intravenous (IV) drug abuse, including the risk of misuse, abuse, and addiction.
7. If the member meets one (1) of the following diagnoses, the prescriber provides attestation that an offer of a referral for substance abuse disorder treatment and care management was made **(a., b., or c.)**:
   a. The member has alcohol use disorder.
   b. The member is an IV drug abuser.
   c. The member has a history of substance abuse within the past 6 months.
8. If the request is for a non-preferred product, the member has a contraindication or is otherwise not a candidate for all preferred regimens (see table below).
9. If the request is for Mavyret for 16 weeks of therapy, the member meets all of the following **(a. and b.)**
   a. The member has HCV genotype 3
   b. The member is interferon-experienced

Table 3. Treatment-Naïve or Interferon-Experienced Pediatrics

HCV Genotype	Cirrhosis Status	Recommended Medication and Duration	
		Preferred Products	Non-Preferred Products
1	No Cirrhosis Compensated	Mavyret x 8 weeks Harvoni x 12 weeks Epclusa x 12 weeks	
	Decompensated	Epclusa + RBV x 12 weeks Harvoni + RBV x 12 weeks	
2	No Cirrhosis Compensated	Mavyret x 8 weeks Epclusa x 12 weeks	Sovaldi + RBV x 12 weeks
	Decompensated	Epclusa + RBV x 12 weeks	
3	No Cirrhosis Compensated	Mavyret x 8 weeks Epclusa x 12 weeks	Sovaldi + RBV x 12 weeks
	Decompensated	Epclusa + RBV x 12 weeks	
4	No Cirrhosis Compensated	Mavyret x 8 weeks Harvoni x 12 weeks Epclusa x 12 weeks	
	Decompensated	Epclusa + RBV x 12 weeks	
5	No Cirrhosis Compensated	Mavyret x 8 weeks Harvoni x 12 weeks Epclusa x 12 weeks	
	Decompensated	Epclusa + RBV x 12 weeks	
6	No Cirrhosis Compensated	Mavyret x 8 weeks Harvoni x 12 weeks Epclusa x 12 weeks	
	Decompensated	Epclusa + RBV x 12 weeks	

*Note: Brand names of medications are used for simplification; prior authorization criteria refer to **brands and any generic formulations (including authorized generics)** available.*

D. Treatment Experienced Pediatrics

When a benefit, coverage of HCV antiviral therapy may be approved when all of the following criteria are met **(1. through 8.)**:

1. The member is between 3 and 17 years of age.
2. The member has a diagnosis of chronic HCV. (ICD-10: B18.2)

3. The prescriber documents any previous therapies the member has used for chronic HCV with reason for discontinuation and/or failure.
4. The prescriber provides the member's cirrhosis status.
5. The member is prescribed an appropriate regimen based on patient characteristics per the FDA-approved labeling and/or AASLD/IDSA guidelines (see table 4. below).
6. The prescriber attests the member or parent/guardian has been educated on the potential adverse effects of alcohol or intravenous (IV) drug abuse, including the risk of misuse, abuse, and addiction.
7. If the member meets one (1) of the following diagnoses, the prescriber provides attestation that an offer of a referral for substance abuse disorder treatment and care management was made **(a., b., or c.)**:
   - **a.** The member has alcohol use disorder.
   - **b.** The member is an IV drug abuser.
   - **c.** The member has a history of substance abuse within the past 6 months.
8. If the request is for a non-preferred product, the member has a contraindication or is otherwise not a candidate for all preferred regimens (see table below).

Table 4. Treatment Experienced Pediatrics

HCV Genotype	Cirrhosis Status	Prior Treatment	Recommended Medication and Duration
1	No Cirrhosis	Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir*	Mavyret x 8 weeks Epclusa x 12 weeks
		NS3/4A protease inhibitors but no NS5A inhibitor	Mavyret x 12 weeks
		NS5A protease inhibitor but no NS5A inhibitor	Mavyret x 16 weeks
		Interferon-based regimen (+/ribavirin) and an HCV protease inhibitor	Harvoni x 12 weeks
	Compensated	Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir*	Mavyret x 12 weeks Epclusa x 12 weeks
		NS3/4A protease inhibitors but no NS5A inhibitor	Mavyret x 12 weeks
		NS5A protease inhibitor but no NS5A inhibitor	Mavyret x 16 weeks
		Interferon-based regimen (+/ribavirin) and an HCV protease inhibitor	Harvoni x 24 weeks
	Decompensated	Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir*	Epclusa + RBV x 12 weeks
2	No Cirrhosis	Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir*	Mavyret x 8 weeks Epclusa x 12 weeks
		NS3/4A protease inhibitors but no NS5A inhibitor	Mavyret x 12 weeks

		NS5A protease inhibitor but no NS5A inhibitor	Mavyret x 16 weeks
	Compensated	Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir*	Mavyret x 12 weeks Epclusa x 12 weeks
		NS3/4A protease inhibitors but no NS5A inhibitor	Mavyret x 12 weeks
		NS5A protease inhibitor but no NS5A inhibitor	Mavyret x 16 weeks
	Decompensated	Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir*	Epclusa + RBV x 12 weeks
3	No Cirrhosis	Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir*	Mavyret x 16 weeks Epclusa x 12 weeks
		NS3/4A protease inhibitors but no NS5A inhibitor	Mavyret x 12 weeks
		NS5A protease inhibitor but no NS5A inhibitor	Mavyret x 16 weeks
	Compensated	Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir*	Mavyret x 16 weeks Epclusa x 12 weeks
		NS3/4A protease inhibitors but no NS5A inhibitor	Mavyret x 12 weeks
		NS5A protease inhibitor but no NS5A inhibitor	Mavyret x 16 weeks
	Decompensated	Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir*	Epclusa + RBV x 12 weeks
4	No Cirrhosis	Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir*	Mavyret x 8 weeks Epclusa x 12 weeks
		NS3/4A protease inhibitors but no NS5A inhibitor	Mavyret x 12 weeks
		NS5A protease inhibitor but no NS5A inhibitor	Mavyret x 16 weeks
		Interferon-based regimen (+/- ribavirin) and an HCV protease inhibitor	Harvoni x 12 weeks
	Compensated	Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir*	Mavyret x 12 weeks Epclusa x 12 weeks
		NS3/4A protease inhibitors but no NS5A inhibitor	Mavyret x 12 weeks
		NS5A protease inhibitor but no NS5A inhibitor	Mavyret x 16 weeks
		Interferon-based regimen (+/ribavirin) and an HCV protease inhibitor	Harvoni x 12 weeks

	Decompensated	Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir*	Epclusa + RBV x 12 weeks
5	No Cirrhosis	Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir*	Mavyret x 8 weeks Epclusa x 12 weeks
		NS3/4A protease inhibitors but no NS5A inhibitor	Mavyret x 12 weeks
		NS5A protease inhibitor but no NS5A inhibitor	Mavyret x 16 weeks
		Interferon-based regimen (+/ribavirin) and an HCV protease inhibitor	Harvoni x 12 weeks
	Compensated	Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir*	Mavyret x 12 weeks Epclusa x 12 weeks
		NS3/4A protease inhibitors but no NS5A inhibitor	Mavyret x 12 weeks
		NS5A protease inhibitor but no NS5A inhibitor	Mavyret x 16 weeks
		Interferon-based regimen (+/ribavirin) and an HCV protease inhibitor	Harvoni x 12 weeks
	Decompensated	Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir*	Epclusa + RBV x 12 weeks
6	No Cirrhosis	Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir*	Mavyret x 8 weeks Epclusa x 12 weeks
		NS3/4A protease inhibitors but no NS5A inhibitor	Mavyret x 12 weeks
		NS5A protease inhibitor but no NS5A inhibitor	Mavyret x 16 weeks
		Interferon-based regimen (+/ribavirin) and an HCV protease inhibitor	Harvoni x 12 weeks
	Compensated	Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir*	Mavyret x 12 weeks Epclusa x 12 weeks
		NS3/4A protease inhibitors but no NS5A inhibitor	Mavyret x 12 weeks
		NS5A protease inhibitor but no NS5A inhibitor	Mavyret x 16 weeks
		Interferon-based regimen (+/ribavirin) and an HCV protease inhibitor	Harvoni x 12 weeks
	Decompensated	Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir*	Epclusa + RBV x 12 weeks

*Note: Brand names of medications are used for simplification; prior authorization criteria refer to **brands and any generic formulations (including authorized generics)** available.*
**No exposure to NS34A or NS5A protease inhibitors*

E. Treatment Naïve Kidney Transplant Patients

When a benefit, coverage of HCV antiviral therapy may be approved when all of the following criteria is met **(1. through 10.)**:

1. The member is 18 years of age or older.
2. The member meets one (1) of the following criteria **(a. or b.)**:
   a. The member has a diagnosis of chronic HCV. (ICD-10: B18.2)
   b. If the request is for Mavyret, the member has a diagnosis of acute (ICD-10: B17) or chronic HCV (ICD-10: B18.2).
3. The member has a history of kidney transplant
4. The member has not received prior HCV treatment.
5. The prescriber provides the member's cirrhosis status.
6. The member is prescribed an appropriate regimen based on patient characteristics per the FDA-approved labeling and/or AASLD/IDSA guidelines (see table 5. below).
7. The prescriber attests the member or parent/guardian has been educated on the potential adverse effects of alcohol or intravenous (IV) drug abuse, including the risk of misuse, abuse, and addiction.
8. If the member meets one (1) of the following diagnoses, the prescriber provides attestation that an offer of a referral for substance abuse disorder treatment and care management was made **(a., b., or c.)**:
   a. The member has alcohol use disorder.
   b. The member is an IV drug abuser.
   c. The member has a history of substance abuse within the past 6 months.
9. The member has had appropriate resistance-associated substitutions (RASs) testing performed, based upon agent and genotype (see table 5. below).
10. If the request is for a non-preferred product, the member has a contraindication or is otherwise not a candidate for all preferred regimens (see table below).

Table 5. Treatment-Naïve Kidney Transplant Patients

HCV Genotype	Cirrhosis Status	Recommended Medication and Duration	
		Preferred Products	Non-Preferred Products
1a	No Cirrhosis Compensated	Mavyret x 12 weeks Harvoni x 12 weeks Epclusa x 12 weeks	Zepatier x 12 weeks without baseline NS5A RASs for elbasvir
	Decompensated	Harvoni + ribavirin x 12 weeks Epclusa x ribavirin x 12 weeks Harvoni x 24 weeks Epclusa x 24 weeks	
1b	No Cirrhosis Compensated	Mavyret x 12 weeks Harvoni x 12 weeks Epclusa x 12 weeks	Zepatier x 12 weeks without baseline NS5A RASs for elbasvir
	Decompensated	Harvoni + ribavirin x 12 weeks Epclusa x ribavirin x 12 weeks Harvoni x 24 weeks Epclusa x 24 weeks	
2	No Cirrhosis Compensated	Mavyret x 12 weeks Epclusa x 12 weeks	
	Decompensated	Epclusa + ribavirin x 12 weeks Epclusa x 24 weeks	
3	No Cirrhosis Compensated	Mavyret x 12 weeks Epclusa x 12 weeks	

	Decompensated	Epclusa + ribavirin x 12 weeks Epclusa x 24 weeks	
4	No Cirrhosis Compensated	Mavyret x 12 weeks Harvoni x 12 weeks Epclusa x 12 weeks	Zepatier x 12 weeks without baseline NS5A RASs for elbasvir
	Decompensated	Harvoni + ribavirin x 12 weeks Epclusa x ribavirin x 12 weeks Harvoni x 24 weeks Epclusa x 24 weeks	
5	No Cirrhosis Compensated	Mavyret x 12 weeks Harvoni x 12 weeks Epclusa x 12 weeks	
	Decompensated	Harvoni + ribavirin x 12 weeks Epclusa x ribavirin x 12 weeks Harvoni x 24 weeks Epclusa x 24 weeks	
6	No Cirrhosis Compensated	Mavyret x 12 weeks Harvoni x 12 weeks Epclusa x 12 weeks	
	Decompensated	Harvoni + ribavirin x 12 weeks Epclusa x ribavirin x 12 weeks Harvoni x 24 weeks Epclusa x 24 weeks	

*Note: Brand names of medications are used for simplification; prior authorization criteria refer to **brands and any generic formulations (including authorized generics)** available.*

F. Treatment Experienced Kidney Transplant Patients

When a benefit, coverage of HCV antiviral therapy may be approved when all of the following criteria is met **(1. through 10.)**:

1. The member is 18 years of age or older.
2. The member has a diagnosis of chronic HCV. (ICD-10: B18.2)
3. The member has a history of a kidney transplant
4. The prescriber documents any previous therapies the member has used for chronic HCV with reason for discontinuation and/or failure.
5. The prescriber provides the member's cirrhosis status.
6. The member is prescribed an appropriate regimen based on patient characteristics per the FDA-approved labeling and/or AASLD/IDSA guidelines (see table 6. below).
7. The prescriber attests the member or parent/guardian has been educated on the potential adverse effects of alcohol or intravenous (IV) drug abuse, including the risk of misuse, abuse, and addiction.
8. If the member meets one (1) of the following diagnoses, the prescriber provides attestation that an offer of a referral for substance abuse disorder treatment and care management was made **(a., b., or c.)**:
   a. The member has alcohol use disorder.
   b. The member is an IV drug abuser.

c. The member has a history of substance abuse within the past 6 months.

9. The member has had appropriate resistance-associated substitutions (RASs) testing performed, based upon agent and genotype (see table 6. below).

10. If the request is for a non-preferred product, the member has a contraindication or is otherwise not a candidate for all preferred regimens (see table 6. below).

Table 6. Treatment Experienced Kidney Transplant Patients

HCV Genotype	Cirrhosis Status	Prior Treatment	Recommended Medication and Duration	
			Preferred Products	Non-Preferred Products
1a	No Cirrhosis	Non-DAA	Mavyret x 12 weeks Harvoni x 12 weeks Epclusa x 12 weeks	Zepatier x 12 weeks without baseline NS5A RASs for elbasvir
		DAA	Vosevi x 12 weeks	
	Compensated	Non-DAA	Mavyret x 12 weeks Harvoni x 12 weeks Epclusa x 12 weeks	Zepatier x 12 weeks without baseline NS5A RASs for elbasvir
		DAA	Vosevi ± ribavirin x 12 weeks	
	Decompensated	Sofosbuvir	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	
		NS5A inhibitor	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	
1b	No Cirrhosis	Non-DAA	Mavyret x 12 weeks Harvoni x 12 weeks Epclusa x 12 weeks	Zepatier x 12 weeks without baseline NS5A RASs for elbasvir
		DAA	Vosevi x 12 weeks	
	Compensated	Non-DAA	Mavyret x 12 weeks Harvoni x 12 weeks Epclusa x 12 weeks	Zepatier x 12 weeks without baseline NS5A RASs for elbasvir
		DAA	Vosevi ± ribavirin x 12 weeks	
	Decompensated	Sofosbuvir	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	
		NS5A inhibitor	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	
2	No Cirrhosis	Non-DAA	Mavyret x 12 weeks Epclusa x 12 weeks	
		DAA	Vosevi x 12 weeks	
	Compensated	Non-DAA	Mavyret x 12 weeks Epclusa x 12 weeks	
		DAA	Vosevi ± ribavirin x 12 weeks	
	Decompensated	Sofosbuvir	Epclusa + ribavirin x 24 weeks	

		NS5A inhibitor	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	
3	No Cirrhosis	Non-DAA	Mavyret x 12 weeks Epclusa x 12 weeks	
		DAA	Vosevi x 12 weeks	
	Compensated	Non-DAA	Mavyret x 12 weeks Epclusa x 12 weeks	
		DAA	Vosevi ± ribavirin x 12 weeks	
	Decompensated	Sofosbuvir	Epclusa + ribavirin x 24 weeks	
		NS5A inhibitor	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	
4	No Cirrhosis	Non-DAA	Mavyret x 12 weeks Harvoni x 12 weeks Epclusa x 12 weeks	Zepatier x 12 weeks without baseline NS5A RASs for elbasvir
		DAA	Vosevi x 12 weeks	
	Compensated	Non-DAA	Mavyret x 12 weeks Harvoni x 12 weeks Epclusa x 12 weeks	Zepatier x 12 weeks without baseline NS5A RASs for elbasvir
		DAA	Vosevi ± ribavirin x 12 weeks	
	Decompensated	Sofosbuvir	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	
		NS5A inhibitor	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	
5	No Cirrhosis	Non-DAA	Mavyret x 12 weeks Harvoni x 12 weeks Epclusa x 12 weeks	
		DAA	Vosevi x 12 weeks	
	Compensated	Non-DAA	Mavyret x 12 weeks Harvoni x 12 weeks Epclusa x 12 weeks	
		DAA	Vosevi ± ribavirin x 12 weeks	
	Decompensated	Sofosbuvir	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	
		NS5A inhibitor	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	
6	No Cirrhosis	Non-DAA	Mavyret x 12 weeks Harvoni x 12 weeks	

			Epclusa x 12 weeks	
		DAA	Vosevi x 12 weeks	
	Compensated	Non-DAA	Mavyret x 12 weeks Harvoni x 12 weeks Epclusa x 12 weeks	
		DAA	Vosevi ± ribavirin x 12 weeks	
	Decompensated	Sofosbuvir	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	
		NS5A inhibitor	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	

*Note: Brand names of medications are used for simplification; prior authorization criteria refer to **brands and any generic formulations (including authorized generics)** available.*

II. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Based on the lack of evidence and guideline support, requests for Viekira Pak will not be authorized.
II. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
III. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

If approved, authorization will be granted for duration as outlined above. If member is already established on therapy, approval duration will only be granted for remaining duration of course of therapy.

Claims for duration of therapy greater than 12 weeks (84 days) will reject at point of sale. PLA will be required to allow payment for duration of therapy greater than 12 weeks (84 days).

Automatic Approval Criteria

None

References:

1. Epclusa [package insert]. Foster City, CA: Gilead Sciences, Inc.; April 2022.
2. Harvoni [package insert]. Foster City, CA: Gilead Sciences, Inc.; December 2024.
3. Mavyret [package insert]. North Chicago, IL: AbbVie Inc.; June 2025.
4. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; December 2024.
5. Viekira Pak [package insert]. North Chicago, IL: AbbVie Inc.; December 2019.
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