Pharmacy Policy Bulletin: J-0820 Hepatitis C Oral Agents – Commercial National Select Formulary				
Number: J-0820	Category: Prior Authorization			
Line(s) of Business:	Benefit(s):			
⊠ Commercial	Commercial:			
☐ Healthcare Reform	Prior Authorization (1.):			
□ Medicare	 Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization 			
	Quantity Limits (1., 2., 3., or 4.):			
	 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			
Degion(s):	4. Rx Mgmt Performance = MRXC = Yes			
Region(s):	Additional Restriction(s): Applies to Commercial National Select formulary only			
⊠ All	Applies to Commercial National Select formulary only			
☐ Delaware				
☐ New York				
☐ Pennsylvania				
☐ West Virginia				
Version: J-0820-017	Original Date: 11/07/2018			
Effective Date: 10/08/2025	Review Date: 09/17/2025			

Drugs	Epclusa (sofosbuvir/velpatasvir) – brand and authorized generic						
Product(s):	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-	Epclusa (sofosbuvir/velpatasvir) is indicated for the treatment adult and pediatric						
Approved	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						
Indication(s):	decompensated cirrhosis for use in combination with ribavirin.						
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	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: in adults without cirrhosis or with compensated cirrhosis, in adults with						
	genotype 1 infection with decompensated cirrhosis in combination with ribavirin,						
	adults with genotype 1 or 4 infection who are liver transplant recipients without						
	cirrhosis or with compensated cirrhosis in combination with ribavirin, and						
	pediatric patients age 3 years and older without cirrhosis or with compensated						
	cirrhosis.						
	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	Daclatasvir	 Dasabuvir
Grazoprevir	Elbasvir	 Sofosbuvir
 Paritaprevir 	 Ledipasvir 	
Simeprevir	Ombitasvir	
Voxilaprevir	 Pibrentasvir 	
	 Velpatasvir 	

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	Patients who had an HCV RNA that did not drop by at
non-responder	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	
Crilid-Pugit B	Impairment	Decompensated
Child Dugh C	Severe Hepatic	Cirrhosis
Child-Pugh C	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.
- 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.
- 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.
- 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.
- Ribavirin should not be used in patients with a creatinine clearance less than 50 ml/min.
- The prescribing clinician is a gastroenterologist, hepatologist, infectious diseases physician, or a transplantation physician.
- 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.

- I. 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 > 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 below).

Table 1. Treatment Naïve Adults				
HCV Genotype	Prior Liver Transplant	Cirrhosis Status	Preferred Products	Non-Preferred Products
1а	No	No Cirrhosis	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	Harvoni AG x 8 weeks Harvoni AG x 12 weeks Mavyret x 8 weeks Epculsa AG x 12 weeks
		Compensated	Harvoni x 12 weeks Epclusa x 12 weeks Zepatier x 12 weeks	Harvoni AG x 12 weeks Epclusa AG x 12 weeks Mavyret x 8 weeks

		Decompensated	Harvoni + ribavirin x 12 weeks Epclusa x ribavirin x 12 weeks Harvoni x 24 weeks Epclusa x 24 weeks	Harvoni AG + ribavirin x 12 weeks Epclusa AG x ribavirin x 12 weeks Harvoni AG x 24 weeks Epclusa AG x 24 weeks
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		Decompensated	Harvoni + ribavirin x 12 weeks Epclusa + ribavirin x 12 weeks	Harvoni AG + ribavirin x 12 weeks Epclusa AG + ribavirin x 12 weeks
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1b		Decompensated	Harvoni + ribavirin x 12 weeks Epclusa x ribavirin x 12 weeks Harvoni x 24 weeks Epclusa x 24 weeks	Harvoni AG + ribavirin x 12 weeks Epclusa AG x ribavirin x 12 weeks Harvoni AG x 24 weeks Epclusa AG x 24 weeks
		No Cirrhosis	Harvoni x 12 weeks Epclusa x 12 weeks	Mavyret x 12 weeks Harvoni AG x 12 weeks Epclusa AG x 12 weeks
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		Decompensated	Harvoni + ribavirin x 12 weeks Epclusa + ribavirin x 12 weeks	Harvoni AG + ribavirin x 12 weeks Epclusa AG + ribavirin x 12 weeks
		No Cirrhosis	Epclusa x 12 weeks	Mavyret x 8 weeks Epclusa AG x 12 weeks
	No	Compensated	Epclusa x 12 weeks	Mavyret x 8 weeks Epclusa AG x 12 weeks
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		No Cirrhosis	Epclusa x 12 weeks	Mavyret x 12 weeks Epclusa AG x 12 weeks
	Yes	Compensated	Epclusa x 12 weeks	Mavyret x 12 weeks Epclusa AG x 12 weeks
		Decompensated	Epclusa + ribavirin x 12 weeks	Epclusa AG + ribavirin x 12 weeks
		No Cirrhosis	Epclusa x 12 weeks	Mavyret x 8 weeks Epclusa AG x 12 weeks
3	No	Compensated	Epclusa x 12 weeks for patients without baseline	Mavyret x 8 weeks Epclusa AG x 12 weeks for patients without baseline

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				weeks	weeks
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I WEEKS					I - 7

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

B. Treatment Experienced Adults

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 Genotyp e	Prior Liver Transpla nt	Cirrhosis Status	Prior Treatment	Preferre d Product s	Non- Preferred Products	
			Sofosbuvir/ribavirin ± interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir	Vosevi x 12 weeks	Mavyret x 16 weeks	
1a	No	No Cirrhosis	Elbasvir/grazoprevir	Vosevi x 12 weeks		

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

				Epclusa x 12	Epclusa AG x 12
			DAA-Experienced	weeks Vosevi x 12 weeks	weeks
	Compensated	Interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon	Harvoni x 12 weeks Epclusa x 12 weeks	Harvoni AG x 12 weeks Epclusa AG x 12 weeks Mavyret x 12 weeks	
			DAA-Experienced	Vosevi ± ribavirin x 12 weeks	
		Decompensate d	All Treatment-Experienced Patients	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	Harvoni AG + ribavirin x 24 weeks Epclusa AG + ribavirin x 24 weeks
		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	Vosevi x 12 weeks	Mavyret + sofosobuv ir + ribavirin x 16 weeks
1b			Sofosbuvir/Velpatasvir/ Voxilaprevir	Vosevi + ribavirin x 24 weeks	Mavyret + sofosobuvi r + ribavirin x 16 weeks
	No		Sofosbuvir + glecaprevir/pibrentasvir	Vosevi + ribavirin x 24 weeks	Mavyret + sofosbuvir + ribavirin x 24 weeks
			Sofosbuvir/ribavirin ± interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir	Vosevi x 12 weeks	Mavyret x 16 weeks
		Compensated	Elbasvir/grazoprevir	Vosevi x 12 weeks	
			Glecaprevir/pibrentasvir	Vosevi + ribavirin x 12 weeks	Mavyret + sofosobuv ir + ribavirin x 16 weeks

			Vosevi +	Mavyret + sofosobuv
		Sofosbuvir/Velpatasvir/ Voxilaprevir	ribavirin x 24 weeks	ir + ribavirin x 16 weeks
		Sofosbuvir + glecaprevir/pibrentasvir	Vosevi + ribavirin x 24 weeks	Mavyret + sofosobuv ir + ribavirin x 24 weeks
	Decompensate	Sofosbuvir	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	Harvoni AG + ribavirin x 24 weeks Epclusa AG + ribavirin x 24 weeks
	d	NS5A inhibitor	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	Harvoni AG + ribavirin x 24 weeks Epclusa AG + ribavirin x 24 weeks
	No Cirrhosis	Interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon	Harvoni x 12 weeks Epclusa x 12 weeks	Mavyret x 12 weeks Harvoni AG x 12 weeks Epclusa AG x 12 weeks
		DAA-Experienced	Vosevi x 12 weeks	
Yes	Yes Compensated Decompensate d	Interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon	Harvoni x 12 weeks Epclusa x 12 weeks	Harvoni AG x 12 weeks Epclusa AG x 12 weeks Mavyret x 12 weeks
		DAA-Experienced	Vosevi ± ribavirin x 12 weeks	
		All Treatment-Experienced Patients	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin	Harvoni AG + ribavirin x 24 weeks Epclusa AG + ribavirin x 24 weeks

				x 24	
				weeks	
			Sofosbuvir/ribavirin ± interferon,	Vosevi x	Mavyret x
			sofosbuvir/ledipasvir, or	12 weeks	16 weeks
			sofosbuvir/velpatasvir		
				Vosevi	
			Elbasvir/grazoprevir	x 12	
				weeks Vosevi x	Mavyret +
				12	sofosobuv
			Glecaprevir/pibrentasvir	weeks	ir +
			' '		ribavirin x
		No Cirrhosis			16 weeks
				Vosevi	Mavyret +
			Sofosbuvir/Velpatasvir/	+	sofosobuv
			Voxilaprevir	ribavirin x 24	ir + ribavirin x
				weeks	16 weeks
				Vosevi	Mavyret +
			Sofosbuvir +	+	sofosobuv
			glecaprevir/pibrentasvir	ribavirin	ir +
			giodapiovii/pibionidovii	x 24	ribavirin x
				Weeks Vosevi x	24 weeks
			Sofosbuvir/ribavirin ± interferon,	12	Mavyret x 16 weeks
			sofosbuvir/ledipasvir, or	weeks	10 WCCK3
		lo Compensated	sofosbuvir/velpatasvir	W GOILG	
			Elbasvir/grazoprevir	Vosevi	
				x 12	
				weeks	
2	No		Glecaprevir/pibrentasvir	Vosevi +	Mavyret +
				ribavirin	sofosobuv ir +
				x 12	ribavirin x
				weeks	16 weeks
			Sofosbuvir/Velpatasvir/ Voxilaprevir	Vosevi	Mavyret +
				+	sofosobuv
				ribavirin	ir +
				x 24 weeks	ribavirin x 16 weeks
				Vosevi	Mavyret +
				+	sofosobuv
			Sofosbuvir +	ribavirin	ir +
			glecaprevir/pibrentasvir	x 24	ribavirin x
				weeks	24 weeks
				Epclusa	Epclusa
			Sofosbuvir	+ ribavirin	AG + ribavirin x
			Golospavii	x 24	24 weeks
				weeks	
				Harvoni	Harvoni
		Decompensate		+	AG +
		d		ribavirin	ribavirin x
				x 24	24 weeks
			NS5A inhibitor	weeks Epclusa	Epclusa AG +
				+	ribavirin x
				ribavirin	24 weeks
				x 24	
				weeks	

		No Cirrhosis	Interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon	Epclusa x 12 weeks	Mavyret x 12 weeks Epclusa AG x 12 weeks
			DAA-Experienced	Vosevi x 12 weeks	
	Yes	Compensated	Interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon	Epclusa x 12 weeks	Epclusa AG x 12 weeks Mavyret x 12 weeks
		Compensated	DAA-Experienced	Vosevi ± ribavirin x 12 weeks	
		Decompensate d	All Treatment-Experienced Patients	Epclusa + ribavirin x 24 weeks	Epclusa AG + 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	Vosevi x 12 weeks	Mavyret + sofosobuv ir + ribavirin x 16 weeks
3			Sofosbuvir/Velpatasvir/ Voxilaprevir	Vosevi + ribavirin x 24 weeks	Mavyret + sofosobuvi r + ribavirin x 16 weeks
			Sofosbuvir + glecaprevir/pibrentasvir	Vosevi + ribavirin x 24 weeks	Mavyret + sofosobuvi r + 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	Vosevi + ribavirin	Mavyret + sofosobuv ir +
			Glecaprevii/pibreritasvii	x 12 weeks	ribavirin x 16 weeks
			Sofosbuvir/Velpatasvir/ Voxilaprevir, sofosbuvir +	Vosevi + ribavirin	Mavyret + sofosobuv ir +
			glecaprevir/pibrentasvir	x 24 weeks Epclusa	ribavirin x 24 weeks Epclusa
		Decompensate	Sofosbuvir	ribavirin x 24 weeks	AG + ribavirin x 24 weeks
		d d	NS5A inhibitor	Epclusa + ribavirin x 24 weeks	Epclusa AG + ribavirin x 24 weeks
		No Cirrhosis	Interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon	Harvoni x 12 weeks Epclusa x 12 weeks	Harvoni AG x 12 weeks Epclusa AG x 12 weeks
			DAA-Experienced	Vosevi x 12 weeks	
	Yes	Yes Compensated Decompensate d	Interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon	Epclusa x 12 weeks	Epclusa AG x 12 weeks Mavyret x 12 weeks
			DAA-Experienced	Vosevi ± ribavirin x 12 weeks	
			All Treatment-Experienced Patients	Epclusa + ribavirin x 24 weeks	Epclusa AG + ribavirin x 24 weeks
			Sofosbuvir/ribavirin ± interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir	Vosevi x 12 weeks	Mavyret x 16 weeks
			Elbasvir/grazoprevir	Vosevi x 12 weeks	
4	No	No Cirrhosis	Glecaprevir/pibrentasvir	Vosevi x 12 weeks	Mavyret + sofosobuv ir + ribavirin x 16 weeks
			Sofosbuvir/Velpatasvir/ Voxilaprevir	Vosevi + ribavirin	Mavyret + sofosobuv ir +

				x 24 weeks	ribavirin x 16 weeks
			Sofosbuvir + glecaprevir/pibrentasvir	Vosevi + ribavirin x 24 weeks	Mavyret + sofosobuv ir + ribavirin x 24 weeks
			Sofosbuvir/ribavirin ± interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir	Vosevi x 12 weeks	Mavyret x 16 weeks
			Elbasvir/grazoprevir	Vosevi x 12 weeks	
	Compensated	Glecaprevir/pibrentasvir	Vosevi + ribavirin x 12 weeks	Mavyret + sofosobuv ir + ribavirin x 16 weeks	
		Sofosbuvir/Velpatasvir/Voxilapr evir	Vosevi + ribavirin x 24 weeks	Mavyret + sofosobuv ir + ribavirin x 16 weeks	
		Sofosbuvir + glecaprevir/pibrentasvir	Vosevi + ribavirin x 24 weeks	Mavyret + sofosobuv ir + ribavirin x 24 weeks	
		Decompensate	Sofosbuvir	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	Harvoni AG + ribavirin x 24 weeks Epclusa AG + ribavirin x 24 weeks
	Decompensate d	NS5A inhibitor	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	Harvoni AG + ribavirin x 24 weeks Epclusa AG + ribavirin x 24 weeks	
	Yes	No Cirrhosis	Interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon	Harvoni x 12 weeks Epclusa x 12 weeks	Mavyret x 12 weeks Harvoni AG x 12 weeks Epclusa AG 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	Harvoni AG x 12 weeks Epclusa AG x 12 weeks Mavyret x 12 weeks	
			DAA-Experienced	Vosevi ± ribavirin x 12 weeks	
		Decompensate d	All Treatment-Experienced Patients	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	Harvoni AG + ribavirin x 24 weeks Epclusa AG + ribavirin x 24 weeks
		No Cirrhosis No Compensated	Sofosbuvir/ribavirin ± interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir Elbasvir/grazoprevir	Vosevi x 12 weeks Vosevi x 12	Mavyret x 16 weeks
			Glecaprevir/pibrentasvir	weeks Vosevi x 12 weeks	Mavyret + sofosobuv ir + ribavirin x 16 weeks
			Sofosbuvir/Velpatasvir/ Voxilaprevir	Vosevi + ribavirin x 24 weeks	Mavyret + sofosobuv ir + ribavirin x 16 weeks
5 No	No		Sofosbuvir + glecaprevir/pibrentasvir	Vosevi + ribavirin x 24 weeks	Mavyret + sofosobuv ir + ribavirin x 24 weeks
			Sofosbuvir/ribavirin ± interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir	Vosevi x 12 weeks	Mavyret x 16 weeks
			Elbasvir/grazoprevir	Vosevi x 12 weeks	
			Glecaprevir/pibrentasvir	Vosevi + ribavirin x 12 weeks	Mavyret + sofosobuv ir + ribavirin x 16 weeks
			Sofosbuvir/Velpatasvir/ Voxilaprevir	Vosevi + ribavirin	Mavyret + sofosobuv ir + ribavirin x 16 weeks

Sofosbuvir + Sofosbuvir + Sofosobuv Harvoni AG + ribavirin X 24 Weeks Epclusa AG x 12 Weeks Epclusa			1		x 24	
Sofosbuvir + glecaprevir/pibrentasvir						
Sofosbuvir + glecaprevir/pibrentasvir						Mayvret +
Sofosbuvir ribavirin x 24						
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			Compensated			
I Vosevi + I						12 weeks
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DAA-Experienced ribavirin				DAA-Experienced		
x 12 weeks				·		
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+ AG +						
ribavirin x						
x 24 24 weeks						
Decompensate All Treatment-Experienced weeks Epclusa			Decompensate	All Treatment-Experienced		
d Patients Epclusa AG +						
+ ribavirin x						ribavirin x
ribavirin 24 weeks						24 weeks
x 24						
weeks	,				weeks	

			Sofosbuvir/ribavirin ± interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir	Vosevi x 12 weeks	Mavyret x 16 weeks
			Elbasvir/grazoprevir	Vosevi x 12 weeks	
		No Cirrhosis	Glecaprevir/pibrentasvir	Vosevi x 12 weeks	Mavyret + sofosobuv ir + ribavirin x 16 weeks
			Sofosbuvir/Velpatasvir/Voxilaprevi r	Vosevi + ribavirin x 24 weeks	Mavyret + sofosbuvir + ribavirin x 16 weeks
			Sofosbuvir + glecaprevir/pibrentasvir	Vosevi + ribavirin x 24 weeks	Mavyret + sofosbuvir + ribavirin x 24 weeks
			Sofosbuvir/ribavirin ± interferon, sofosbuvir/ledipasvir, or sofosbuvir/velpatasvir	Vosevi x 12 weeks	Mavyret x 16 weeks
		Compensated	Elbasvir/grazoprevir	Vosevi x 12 weeks	
6	No		Glecaprevir/pibrentasvir	Vosevi + ribavirin x 12 weeks	Mavyret + sofosobuv ir + ribavirin x 16 weeks
			Sofosbuvir/Velpatasvir/ Voxilaprevir	Vosevi + ribavirin x 24 weeks	Mavyret + sofosobuv ir + ribavirin x 16 weeks
		Sofosbuvir + glecaprevir/pibrentasvir	Vosevi + ribavirin x 24 weeks	Mavyret + sofosobuv ir + ribavirin x 16 weeks	
			Sofosbuvir	Harvoni + ribavirin x 24 weeks Epclusa +	Harvoni AG + ribavirin x 24 weeks Epclusa AG + ribavirin x
		Decompensate d		ribavirin x 24 weeks	24 weeks
			NS5A inhibitor	Harvoni + ribavirin x 24 weeks Epclusa +	Harvoni AG + ribavirin x 24 weeks Epclusa AG + ribavirin x
				ribavirin	24 weeks

		No Cirrhosis	Interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon	x 24 weeks Harvoni x 12 weeks Epclusa x 12 weeks	Mavyret x 12 weeks Harvoni AG x 12 weeks Epclusa AG x 12 weeks
			DAA-Experienced	Vosevi x 12 weeks	
	Yes	Compensated	Interferon, Peginterferon +/- ribavirin, or sofosbuvir + ribavirin +/- peginterferon	Harvoni x 12 weeks Epclusa x 12 weeks	Harvoni AG x 12 weeks Epclusa AG x 12 weeks Mavyret x 12 weeks
			DAA-Experienced	Vosevi ± ribavirin x 12 weeks	
		Decompensate d	Treatment-Experienced Patients	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	Harvoni AG + ribavirin x 24 weeks Epclusa AG + ribavirin x 24 weeks

^{*}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 criteria (a. and b.)
 - a. The member has HCV genotype 3
 - b. The member is interferon-experienced

	Table 3. Treatment or Inter	feron-Experienced Naïve Pe	ediatrics
HCV Genotype	Cirrhosis Status	Preferred Products	Non-Preferred Products
	No Cirrhosis Compensated	Harvoni x 12 weeks Epclusa x 12 weeks	Mavyret x 8 weeks Harvoni AG x 12 weeks Epclusa AG x 12 weeks
1	Decompensated	Epclusa + RBV x 12 weeks Harvoni + RBV x 12 weeks	Epclusa AG + RBV x 12 weeks Harvoni AG + RBV x 12 weeks
2	No Cirrhosis Compensated	Epclusa x 12 weeks	Sovaldi + RBV x 12 weeks Mavyret x 8 weeks Epclusa AG x 12 weeks
	Decompensated	Epclusa + RBV x 12 weeks	Epclusa AG + RBV x 12 weeks
3	No Cirrhosis Compensated	Epclusa x 12 weeks	Sovaldi + RBV x 12 weeks Mavyret x 8 weeks Epclusa AG x 12 weeks
	Decompensated	Epclusa + RBV x 12 weeks	Epclusa AG + RBV x 12 weeks
4	No Cirrhosis Compensated	Harvoni x 12 weeks Epclusa x 12 weeks	Mavyret x 8 weeks Harvoni AG x 12 weeks Epclusa AG x 12 weeks
	Decompensated	Epclusa + RBV x 12 weeks	Epclusa AG + RBV x 12 weeks
5	No Cirrhosis Compensated	Harvoni x 12 weeks Epclusa x 12 weeks	Mavyret x 8 weeks Harvoni AG x 12 weeks Epclusa AG x 12 weeks
	Decompensated	Epclusa + RBV x 12 weeks	Epclusa AG + RBV x 12 weeks
6	No Cirrhosis Compensated	Harvoni x 12 weeks Epclusa x 12 weeks	Mavyret x 8 weeks Harvoni AG x 12 weeks Epclusa AG x 12 weeks
-	Decompensated	Epclusa + RBV x 12 weeks	Epclusa AG+ RBV x 12 weeks

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 Ex	perienced Pediatrics		
HCV Genotype	Cirrhosis Status	Prior Treatment	Preferred	Non- Preferred
	No Cirrhosis	Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir* NS3/4A protease inhibitors but no NS5A	Epclusa x 12 weeks	Mavyret x 8 weeks Epclusa AG x 12 weeks Mavyret x 12 weeks
		inhibitor NS5A protease inhibitor but no NS5A inhibitor		Mavyret x 16 weeks
		Interferon-based regimen (+/ribavirin) and an HCV protease inhibitor	Harvoni x 12 weeks	Harvoni AG x 12 weeks
1	Compensated	Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir* NS3/4A protease inhibitors but no NS5A	Epclusa x 12 weeks	Mavyret x 12 weeks Epclusa AG x 12 weeks Mavyret x 12 weeks
		inhibitor NS5A protease inhibitor but no NS5A inhibitor Interferon-based	Harvoni x 24 weeks	Mavyret x 16 weeks Harvoni AG x 24
		regimen (+/ribavirin) and an HCV protease inhibitor	TIAIVOIII X 24 WEEKS	weeks
	Decompensated	Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir*	Epclusa + RBV x 12 weeks	Epclusa AG + RBV x 12 weeks
	No Cirrhosis	Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir*	Epclusa x 12 weeks	Mavyret x 8 weeks Epclusa AG x 12 weeks
2		NS3/4A protease inhibitors but no NS5A inhibitor		Mavyret x 12 weeks
2		NS5A protease inhibitor but no NS5A inhibitor		Mavyret x 16 weeks
	Compensated	Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir*	Epclusa x 12 weeks	Mavyret x 12 weeks Epclusa AG 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	Epclusa AG + RBV x 12 weeks
	No Cirrhosis	Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir* NS3/4A protease	Epclusa x 12 weeks	Mavyret x 16 weeks Epclusa AG x 12 weeks Mavyret x 12
		inhibitors but no NS5A inhibitor NS5A protease		weeks Mavyret x 16
		inhibitor but no NS5A inhibitor		weeks
3	Compensated	Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir*	Epclusa x 12 weeks	Mavyret x 16 weeks Epclusa AG 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	Epclusa + RBV x 12 weeks	Epclusa AG + RBV x 12 weeks
		Sofosbuvir*		
	No Cirrhosis	Sofosbuvir* Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir*	Epclusa x 12 weeks	Mavyret x 8 weeks Epclusa AG x 12 weeks
	No Cirrhosis	Sofosbuvir* Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir* NS3/4A protease inhibitors but no NS5A inhibitor	-	weeks Epclusa AG x 12
	No Cirrhosis	Sofosbuvir* Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir* NS3/4A protease inhibitors but no NS5A	-	weeks Epclusa AG x 12 weeks Mavyret x 12
4	No Cirrhosis	Sofosbuvir* Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir* NS3/4A protease inhibitors but no NS5A inhibitor NS5A protease inhibitor but no NS5A	-	weeks Epclusa AG x 12 weeks Mavyret x 12 weeks Mavyret x 16
4	No Cirrhosis Compensated	Sofosbuvir* Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir* NS3/4A protease inhibitors but no NS5A inhibitor NS5A protease inhibitor but no NS5A inhibitor Interferon-based regimen (+/- ribavirin) and an HCV protease	weeks	weeks Epclusa AG x 12 weeks Mavyret x 12 weeks Mavyret x 16 weeks Harvoni AG x 12 weeks Mavyret x 12 weeks Epclusa AG x 12 weeks
4		Sofosbuvir* Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir* NS3/4A protease inhibitors but no NS5A inhibitor NS5A protease inhibitor but no NS5A inhibitor Interferon-based regimen (+/- ribavirin) and an HCV protease inhibitor Interferon-based regimen (+/- ribavirin) and /or Sofosbuvir* NS3/4A protease inhibitors but no NS5A inhibitor	Harvoni x 12 weeks Epclusa x 12	weeks Epclusa AG x 12 weeks Mavyret x 12 weeks Mavyret x 16 weeks Harvoni AG x 12 weeks Mavyret x 12 weeks Epclusa AG x 12 weeks Harvoni AG x 12 weeks Epclusa AG x 12 weeks
4		Sofosbuvir* Interferon-based regimen (+/- ribavirin) and/or Sofosbuvir* NS3/4A protease inhibitors but no NS5A inhibitor NS5A protease inhibitor but no NS5A inhibitor Interferon-based regimen (+/- ribavirin) and an HCV protease inhibitor Interferon-based regimen (+/- ribavirin) and /or Sofosbuvir* NS3/4A protease inhibitors but no NS5A	Harvoni x 12 weeks Epclusa x 12 weeks	weeks Epclusa AG x 12 weeks Mavyret x 12 weeks Mavyret x 16 weeks Harvoni AG x 12 weeks Mavyret x 12 weeks Epclusa AG x 12 weeks Harvoni AG x 12

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

^{*}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	Preferred Products	Non-Preferred Products		
	No Cirrhosis	Zepatier x 12 weeks without			
		baseline NS5A RASs for	Mavyret x 12 weeks		
		elbasvir	Harvoni AG x 12 weeks		
	Compensated	Harvoni x 12 weeks	Epclusa AG x 12 weeks		
		Epclusa x 12 weeks			
1a					
l la		Harvoni + ribavirin x 12	Harvoni AG + ribavirin x 12		
		weeks	weeks		
	Decompensated	Epclusa x ribavirin x 12	Epclusa AG x ribavirin x 12		
		weeks	weeks		
		Harvoni x 24 weeks	Harvoni AG x 24 weeks		
		Epclusa x 24 weeks	Epclusa AG x 24 weeks		
1b	No Cirrhosis	Harvoni x 12 weeks	Mavyret x 12 weeks		
	Compensated	Epclusa x 12 weeks	Harvoni AG x 12 weeks		
			Epclusa AG x 12 weeks		

<u></u>	1		
		Zepatier x 12 weeks without baseline NS5A RASs for	
		elbasvir	
	Decompensated	Harvoni + ribavirin x 12 weeks	Harvoni AG + ribavirin x 12 weeks
		Epclusa x ribavirin x 12 weeks	Epclusa AG x ribavirin x 12 weeks
		Harvoni x 24 weeks Epclusa x 24 weeks	Harvoni AG x 24 weeks Epclusa AG x 24 weeks
2	No Cirrhosis	Epclusa x 12 weeks	Mavyret x 12 weeks
	Compensated	Ī	Epclusa AG x 12 weeks
	Decompensated	Epclusa + ribavirin x 12 weeks	Epclusa AG + ribavirin x 12 weeks
2	No Cimboois	Epclusa x 24 weeks	Epclusa AG x 24 weeks
3	No Cirrhosis Compensated	Epclusa x 12 weeks	Mavyret x 12 weeks Epclusa AG x 12 weeks
	Componicatou		polese //e // /_ mooke
	Decompensated	Epclusa + ribavirin x 12	Epclusa AG + ribavirin x 12
		weeks	weeks
4	N - Oisselsis	Epclusa x 24 weeks	Epclusa AG x 24 weeks
4	No Cirrhosis	Zepatier x 12 weeks without baseline NS5A RASs for	Mavyret x 12 weeks Harvoni AG x 12 weeks
	Compensated	elbasvir	Epclusa AG x 12 weeks
		Harvoni x 12 weeks	Epolada / G X 12 Wooks
		Epclusa x 12 weeks	
	Decompensated	Harvoni + ribavirin x 12	Harvoni AG + ribavirin x 12
	Decompensated	weeks	weeks
		Epclusa x ribavirin x 12	Epclusa AG x ribavirin x 12
		weeks	weeks
		Harvoni x 24 weeks	Harvoni AG x 24 weeks
-	N - Oisselsis	Epclusa x 24 weeks	Epclusa AG x 24 weeks
5	No Cirrhosis	Harvoni x 12 weeks	Mavyret x 12 weeks Harvoni AG x 12 weeks
	Compensated	Epclusa x 12 weeks	Epclusa AG x 12 weeks
			Lpcidsa AG X 12 WCCRs
	Decompensated	Harvoni + ribavirin x 12 weeks	Harvoni AG + ribavirin x 12 weeks
		Epclusa x ribavirin x 12 weeks	Epclusa AG x ribavirin x 12 weeks
		Harvoni x 24 weeks	Harvoni AG x 24 weeks
		Epclusa x 24 weeks	Epclusa AG x 24 weeks
6	No Cirrhosis	Harvoni x 12 weeks	Mavyret x 12 weeks
	Compensated	Epclusa x 12 weeks	Harvoni AG x 12 weeks
			Epclusa AG x 12 weeks
	Decompensated	Harvoni + ribavirin x 12	Harvoni AG+ ribavirin x 12 weeks
		weeks	Epclusa AG x ribavirin x 12
		Epclusa x ribavirin x 12	weeks
		weeks	Harvoni AG x 24 weeks
		Harvoni x 24 weeks Epclusa x 24 weeks	Epclusa AG x 24 weeks
	1	Lhoinsa v 74 Mccvs	

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	Preferred Products	Non-Preferred Products	
	No Cirrhosis	Non-DAA	Zepatier x 12 weeks without baseline NS5A RASs for elbasvir Harvoni x 12 weeks Epclusa x 12 weeks	Mavyret x 12 weeks Harvoni x 12 weeks Epclusa x 12 weeks	
		DAA	Vosevi x 12 weeks		
1a	Compensated	Non-DAA	Zepatier x 12 weeks without baseline NS5A RASs for elbasvir Harvoni x 12 weeks Epclusa x 12 weeks	Mavyret x 12 weeks Harvoni AG x 12 weeks Epclusa AG x 12 weeks	
		DAA	Vosevi ± ribavirin x 12 weeks		
	Decompensated	Sofosbuvir	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	Harvoni AG + ribavirin x 24 weeks Epclusa AG + ribavirin x 24 weeks	
		NS5A inhibitor	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	Harvoni AG + ribavirin x 24 weeks Epclusa AG + ribavirin x 24 weeks	
1b	No Cirrhosis	Non-DAA	Zepatier x 12 weeks without baseline NS5A RASs for elbasvir Harvoni x 12 weeks Epclusa x 12 weeks	Mavyret x 12 weeks Harvoni AG x 12 weeks Epclusa AG x 12 weeks	
		DAA	Vosevi x 12 weeks		
	Compensated	Non-DAA	Zepatier x 12 weeks without baseline NS5A RASs for elbasvir Harvoni x 12 weeks	Mavyret x 12 weeks Harvoni AG x 12 weeks Epclusa AG x 12 weeks	

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

		DAA	Vosevi x 12 weeks	
	Compensated	Non-DAA	Harvoni x 12 weeks Epclusa x 12 weeks	Mavyret x 12 weeks Harvoni AG x 12 weeks Epclusa AG x 12 weeks
	·	DAA	Vosevi ± ribavirin x 12 weeks	
	Decompensated	Sofosbuvir	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	Harvoni AG + ribavirin x 24 weeks Epclusa AG + ribavirin x 24 weeks
		NS5A inhibitor	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	Harvoni AG + ribavirin x 24 weeks Epclusa AG + ribavirin x 24 weeks
	No Cirrhosis	Non-DAA	Harvoni x 12 weeks Epclusa x 12 weeks	Mavyret x 12 weeks Harvoni AG x 12 weeks Epclusa AG x 12 weeks
		DAA	Vosevi x 12 weeks	
	Compensated	Non-DAA	Harvoni x 12 weeks Epclusa x 12 weeks	Mavyret x 12 weeks Harvoni AG x 12 weeks Epclusa AG x 12 weeks
6		DAA	Vosevi ± ribavirin x 12 weeks	
	Decemposated	Sofosbuvir	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	Harvoni AG + ribavirin x 24 weeks Epclusa AG + ribavirin x 24 weeks
	Decompensated —	NS5A inhibitor	Harvoni + ribavirin x 24 weeks Epclusa + ribavirin x 24 weeks	Harvoni AG + ribavirin x 24 weeks Epclusa AG + ribavirin x 24 weeks

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 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.
- 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.
- Viekira Pak [package insert]. North Chicago, IL: AbbVie Inc.; December 2019.
- 6. Vosevi [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2019.
- 7. Zepatier [package insert]. Whitehouse Station, NJ: Merck Inc.; December 2021.
- 8. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Accessed July 7, 2025.
- 9. Centers for Disease Control and Prevention. Hepatitis C Information. Available at: https://www.cdc.gov/hepatitis/hcv/. Accessed July 7, 2025.
- 10. Schlendorf KH, Zalawadiya S, Shah AS, et al. Early outcomes using hepatitis C-positive donors for cardiac transplantation in the era of effective direct-acting anti-viral therapies. J Heart Lung Transplant. 2018; 37:763-69.
- 11. Woolley AE, Singh SK, Goldberg HJ, et al. Heart and lung transplants from HCV-infected donors to uninfected recipients. N Engl J Med. 2019; Apr 3.
- 12. Treatment of HCV-Uninfected Transplant Recipients Receiving Organs From HCV-Viremic Donors: HCV Guidance. Treatment of HCV-Uninfected Transplant Recipients Receiving Organs From HCV-Viremic Donors | HCV Guidance. Available at: https://www.hcvguidelines.org/unique-populations/organs-from-hcv-viremic. Accessed July 7, 2025.

