

Applicable Drugs: Epclusa (sofosbuvir-velpatasvir), Harvoni (ledipasvir-sofosbuvir), ledipasvir-sofosbuvir, Mavyret (glecaprevir-pibrentasvir), sofosbuvir-velpatasvir, Sovaldi (sofosbuvir), Vosevi (sofosbuvir-velpatasvir-voxilaprevir), Zepatier (elbasvir-grazoprevir)

Preferred: Mavyret

Non-preferred: N/A

Date of Origin: 12/11/2023

Date Last Reviewed / Revised: 11/4/2025

Formulary Shield (Excluded): Epclusa 400-100, Harvoni 90-400

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through VII are met)

- I. Diagnosis of one of the following conditions A or B AND must meet all criteria listed under the applicable diagnosis:
 - A. Chronic hepatitis C virus (HCV) infection
 - B. Acute HCV infection
 - i. Request is for Mavyret.
- II. The following clinical information must be submitted:
 - A. Baseline quantitative HCV-RNA test level
 - i. Required for HCV genotype 1a only: NS5A HCV resistance-associated substitution (RAS) testing
 - B. Fibrosis assessment using one or more of the following:
 - i. FIB-4 score
 - ii. FibroScan
 - iii. FibroSure
 - iv. Liver biopsy
 - C. Hepatitis C treatment history (if applicable)
 - D. Hepatitis B surface antigen testing.
- III. Age 3 years or older.
- IV. Patient meets ALL criteria listed under the requested medication:
 - A. Epclusa (sofosbuvir-velpatasvir)
 - i. Documentation of HCV genotype 1, 2, 3, 4, 5, or 6.
 - ii. In patients with no cirrhosis or compensated cirrhosis: documented failure, intolerance, or contraindication to Mavyret.
 - B. Harvoni (ledipasvir-sofosbuvir)

- i. Documentation of HCV genotype 1, 4, 5, or 6.
 - ii. Documented failure, intolerance, or contraindication to both Mavyret and Epclusa.
 - C. Mavyret (glecaprevir-pibrentasvir)
 - i. Documentation of HCV genotype 1, 2, 3, 4, 5, or 6.
 - D. Sovaldi (sofosbuvir)
 - i. Age 3 to 17 years:
 - 1. Documentation of HCV genotype 2 or 3.
 - ii. Age 18 years and older:
 - 1. Documentation of HCV genotype 1, 2, 3 or 4.
 - iii. Documented failure, intolerance, or contraindication to both Mavyret and Epclusa.
 - E. Vosevi (sofosbuvir-velpatasvir-voxilaprevir)
 - i. Age 18 years and older.
 - ii. Previous treatment for HCV satisfying ONE of the following (1 or 2):
 - 1. Documentation of HCV genotype 1, 2, 3, 4, 5, or 6 and previously treated with an HCV regimen including an NS5A inhibitor.
 - 2. Documentation of HCV genotype 1a or 3 and previously treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor.
 - iii. Documented failure, intolerance, or contraindication to Mavyret.
 - F. Zepatier (elbasvir-grazoprevir)
 - i. Age 12 years or older and weighing at least 30 kg.
 - ii. Documentation of HCV genotype 1 or 4.
 - iii. Documented failure, intolerance, or contraindication to Mavyret.
- V. Medication is prescribed in accordance with FDA labeling and is supported by current clinical practice guidelines.
- VI. Treatment must be prescribed by or in consultation with a gastroenterologist, infectious disease specialist, or hepatologist.
- VII. Refer to the plan document for the list of preferred products. If the requested agent is not a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Epclusa: Retreatment in cases of relapse or non-response to a prior treatment course of Epclusa or Vosevi.
- Harvoni: Retreatment in cases of relapse or non-response to a prior treatment course of Epclusa, Harvoni, Mavyret, Vosevi, or Zepatier.
- Mavyret:
 - Retreatment in cases of relapse or non-response to a prior treatment course of Mavyret, Vosevi, or Zepatier.
 - In patients with HCV genotype 1, prior treatment with regimen containing BOTH an HCV NS5A inhibitor and a regimen containing an NS3/4A protease inhibitor (e.g., elbasvir/grazoprevir).
 - Moderate or severe hepatic impairment (Child-Pugh B or C) or history of prior hepatic decompensation (e.g., Child-Turcotte-Pugh score ≥ 7 or history of complications of cirrhosis).
 - Coadministration with atazanavir or rifampin.
- Sovaldi:
 - Retreatment in cases of relapse or non-response to a prior treatment course of Epclusa, Harvoni, Mavyret, Vosevi, or Zepatier.
 - Moderate or severe hepatic impairment (Child-Pugh B or C) or history of prior hepatic decompensation (e.g., Child-Turcotte-Pugh score ≥ 7 or history of complications of cirrhosis).
- Vosevi:
 - Retreatment in cases of relapse or non-response to a prior treatment course of Vosevi.
 - Moderate or severe hepatic impairment (Child-Pugh B or C) or history of prior hepatic decompensation (e.g., Child-Turcotte-Pugh score ≥ 7 or history of complications of cirrhosis).
 - Coadministration with rifampin.
- Zepatier:
 - Retreatment in cases of relapse or non-response to a prior treatment course of Epclusa, Harvoni, Mavyret, Sovaldi, Vosevi, or Zepatier.
 - Moderate or severe hepatic impairment (Child-Pugh B or C) or history of prior hepatic decompensation (e.g., Child-Turcotte-Pugh score ≥ 7 or history of complications of cirrhosis).
 - Coadministration with OATP1B1/3 inhibitors that are known or expected to significantly increase grazoprevir plasma concentrations, strong CYP3A inducers, or efavirenz.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Epclusa
 - Age > 6 years OR weight > 30 kg: 28 tablets per 28 days.
 - Age 3 to 6 years AND weight < 30 kg: 28 oral pellet packets per 28 days.
 - Age 3 to 6 years AND weight > 30 kg: 28 tablets OR up to 56 oral pellet packets per 28 days.
- Harvoni
 - Age > 18 years OR weight > 35 kg: 56 tablets or pellet packets per 28 days.
 - Age 3 or older weighing 17 to 35 kg: 28 tablets or pellet packets per 28 days.
 - Age 3 or older weighing < 17 kg: 28 pellet packets per 28 days.
- Mavyret
 - Weight > 45 kg OR Age > 12 years: 84 tablets per 28 days.
 - Weight >45 kg and documented inability to swallow tablets: 168 pellet packets per 28 days.
 - Pediatric with weight 30 to 45 kg: 140 oral pellet packets per 28 days.
 - Pediatric with weight 20 to 30 kg: 112 oral pellet packets per 28 days.
 - Pediatric with weight less than 20 kg: 84 oral pellet packets per 28 days.
- Sovaldi
 - Patient weight ≥ 35 kg: 28 tablets or 56 pellet packets per 28 days.
 - Patient weight < 35 kg: 28 tablets or pellet packets per 28 days.
- Vosevi: 28 tablets per 28 days.
- Zepatier: 28 tablets per 28 days.

APPROVAL LENGTH

- **Authorization:** See Appendix Tables 1–6 below, or per dosing and treatment duration specified in the FDA-approved prescribing information for the requested drug.
- **Re-Authorization:** N/A

APPENDIX

Table 1. Epclusa treatment recommendations and approval length

Treatment Naive					
Genotype	No Cirrhosis	Compensated Cirrhosis (Child-Pugh A)	Decompensated Cirrhosis (Child-Pugh B or C)	Post-liver transplant with no cirrhosis or compensated cirrhosis	Post-liver transplant with decompensated cirrhosis
1, 2, 4, 5, 6	12 weeks	12 weeks	RBV ineligible: 24 weeks	12 weeks	EPC/RBV x 12 weeks
			RBV eligible: EPC/RBV x 12 weeks		
3	12 weeks	(-) NS5RA RAS Y93H for VEL: 12 weeks	RBV ineligible: 24 weeks	12 weeks	EPC/RBV x 12 weeks
		(+) NS5RA RAS Y93H for VEL: EPC/RBV x 12 weeks	RBV eligible: EPC/RBV x 12 weeks		
Treatment Experienced					
Genotype	No Cirrhosis	Compensated Cirrhosis (Child-Pugh A)	Decompensated Cirrhosis (Child-Pugh B or C)	Post-liver transplant with no cirrhosis or compensated cirrhosis	Post-liver transplant with decompensated cirrhosis
1, 2, 3, 4, 5, 6	12 weeks ^a	12 weeks ^a	EPC/RBV x 12 weeks ^a EPC/RBV x 24 weeks ^b	12 weeks	EPC/RBV x 24 weeks

^aPrior treatment with peginterferon alfa/ribavirin with or without an HCV NS3/4A protease inhibitor (boceprevir, simeprevir, or telaprevir).

^bPrior sofosbuvir- or NS5A inhibitor-based treatment failure.

Abbreviations: (-), negative baseline; (+), positive baseline; EPC, Epclusa; NS5RA RAS Y93H for VEL, Non-structural protein 5A inhibitor resistance-associated substitution Y93H for velpatasvir; RBV; ribavirin.

Table 2. Harvoni Treatment Recommendations and Approval Length

Treatment Naive					
Genotype	No Cirrhosis	Compensated Cirrhosis (Child-Pugh A)	Decompensated Cirrhosis (Child-Pugh B or C)	Post-liver transplant with no cirrhosis or compensated cirrhosis	Post-liver transplant with decompensated cirrhosis
1	HIV (-) & HCV-RNA level < 6 million IU/mL: 8 weeks	12 weeks	RBV ineligible: 24 weeks	12 weeks ^e OR HAR/RBV x 12 weeks ^f	HAR/RBV x 12 weeks
	All others: 12 weeks		RBV eligible: HAR/RBV x 12 weeks		
4	HCV -RNA level < 6 million IU/mL without G4r: 8 weeks	12 weeks	RBV ineligible: 24 weeks	12 weeks ^e OR HAR/RBV x 12 weeks ^f	HAR/RBV x 12 weeks
	All others: 12 weeks		RBV eligible: HAR/RBV x 12 weeks		
5, 6	12 weeks	12 weeks	RBV ineligible: 24 weeks	12 weeks	HAR/RBV x 12 weeks
			RBV eligible: HAR/RBV x 12 weeks		
Treatment Experienced					

Genotype	No Cirrhosis	Compensated Cirrhosis (Child-Pugh A)	Decompensated Cirrhosis (Child-Pugh B or C)	Post-liver transplant with no cirrhosis or compensated cirrhosis	Post-liver transplant with decompensated cirrhosis
1	12 weeks	24 weeks	RBV ineligible: 24 weeks RBV eligible: HAR/RBV x 12 weeks HAR/RBV x 24 weeks ^d	12 weeks ^e OR HAR/RBV x 12 weeks ^f	HAR/RBV x 24 weeks ^e
4	12 weeks	12 weeks	RBV ineligible: 24 weeks RBV eligible: HAR/RBV x 12 weeks HAR/RBV x 24 weeks ^d	12 weeks ^e OR HAR/RBV x 12 weeks ^f	HAR/RBV x 24 weeks ^e
5, 6	12 weeks ^c	12 weeks ^c	RBV ineligible: 24 weeks RBV eligible: HAR/RBV x 12 weeks HAR/RBV x 24 weeks ^d	12 weeks ^e	HAR/RBV x 24 weeks ^e

^cNot recommended for genotype 6e subtype.

^dPrior sofosbuvir- or NS5A inhibitor-based treatment failure.

^eRecommendation from the American Association for the Study of Liver Diseases – Infectious Diseases Society of America. Recommendations for testing, managing, and treating hepatitis C Guidance.

^fRecommendation from Harvoni prescribing information.

Abbreviations: G4r, genotype 4r subtype; HAR, Harvoni; HCV, hepatitis C virus; HIV (-), human immunodeficiency virus negative; RBV, ribavirin.

Table 3. Mavyret Treatment Recommendations and Approval Length

Treatment Naïve			
Genotype	No Cirrhosis	Compensated Cirrhosis (Child-Pugh A)	Post-liver transplant with no cirrhosis or compensated cirrhosis
1, 2, 3, 4, 5, 6	8 weeks	8 weeks	12 weeks

Treatment-naïve patients are those who have not received treatment for the current infection.

Treatment Experienced			
Genotype	Previously Treated With	No Cirrhosis	Compensated Cirrhosis
1	An NS5A inhibitor without prior treatment with an NS3/4A protease	16 weeks	16 weeks
	An NS3/4A PI3 without prior treatment with an NS5A inhibitor	12 weeks	12 weeks
1, 2, 4, 5, 6	PRS	8 weeks	12 weeks
3	PRS	16 weeks	16 weeks

Prior NS3/4A protease inhibitor treatment without an NS5A inhibitor (i.e., simeprevir and sofosbuvir, or simeprevir, boceprevir, or telaprevir with peginterferon and ribavirin).

Prior NS5A inhibitor treatment without an NS3/4A protease inhibitor (i.e., ledipasvir and sofosbuvir or daclatasvir with peginterferon and ribavirin).

PRS=Prior treatment experience with regimens containing (peg) interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor.

Table 4. Sovaldi Treatment Recommendations and Approval Length

Treatment Naïve			
Genotype	No Cirrhosis	Compensated Cirrhosis (Child-Pugh A)	Hepatocellular Carcinoma Awaiting Liver Transplant
1	INF ineligible: SOV/RBV x 24 weeks	INF ineligible: SOV/RBV x 24 weeks	SOV/RBV up to 48 weeks or the time of liver transplantation (whichever comes first)
	INF eligible: SOV/PEG INF alfa/RBV x 12 weeks	INF eligible: SOV/PEG INF alfa/RBV x 12 weeks	
2	SOV/RBV x 12 weeks	SOV/RBV x 12 weeks	SOV/RBV up to 48 weeks or the time of liver transplantation (whichever comes first)
3	SOV/RBV x 24 weeks	SOV/RBV x 24 weeks	SOV/RBV up to 48 weeks or the time of liver transplantation (whichever comes first)
4	SOV/PEG INF alfa/RBV x 12 weeks	SOV/PEG INF alfa/RBV x 12 weeks	SOV/RBV up to 48 weeks or the time of liver transplantation (whichever comes first)
Treatment Experienced			
Genotype	No Cirrhosis	Compensated Cirrhosis (Child-Pugh A)	Hepatocellular Carcinoma Awaiting Liver Transplant
2	SOV/RBV x 12 weeks ^k	SOV/RBV x 12 weeks ^k	SOV/RBV up to 48 weeks or the time of liver transplantation (whichever comes first)
3	SOV/RBV x 24 weeks ^k	SOV/RBV x 24 weeks ^k	SOV/RBV up to 48 weeks or the time of liver transplantation (whichever comes first)

^kFailure of an interferon-based regimen with or without ribavirin.

Abbreviations: INF, interferon; PEG INF alfa, peginterferon alfa; RBV, ribavirin; SOV, Sovaldi.

Table 5. Vosevi Treatment Recommendations and Approval Length

Treatment Experienced		
Genotype	No Cirrhosis	Compensated Cirrhosis (Child-Pugh A)
1, 2	VOS x 12 weeks ^{l,m,o} VOS/RBV x 24 weeks ^p	VOS x 12 weeks ^{l,m,o} VOS/RBV x 24 weeks ^p
3	VOS x 12 weeks ^{l,m,o} VOS/RBV x 24 weeks ^p	VOS x 12 weeks ^{l,m,o} VOS/RBV x 24 weeks ^p RBV ineligible: VOS x 24 weeks ⁿ RBV eligible: VOS/RBV x 12 weeks ⁿ
4, 5, 6	VOS x 12 weeks ^{l,m,o} VOS/RBV x 24 weeks ^p	VOS x 12 weeks ^{l,m,o} VOS/RBV x 24 weeks ^p

^lPrior treatment with NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir).

^mPrior treatment sofosbuvir with or without peginterferon alfa/ribavirin, ribavirin, or HCV NS3/4A protease inhibitor (boceprevir, simeprevir, or telaprevir).

ⁿPrior treatment with sofosbuvir/velpatasvir and baseline NS5A RAS Y93H for velpatasvir.

^oPrior treatment with glecaprevir/pibrentasvir

^pPrior multiple direct acting antivirals treatment failure, including sofosbuvir plus glecaprevir/pibrentasvir

Abbreviations: RBV, ribavirin; VOS, Vosevi.

Table 6. Zepatier Treatment Recommendations and Approval Length

Genotype	No Cirrhosis	Compensated Cirrhosis (Child-Pugh A)
1a	12 weeks	12 weeks
1b	12 weeks	12 weeks
4	12 weeks	12 weeks
Genotype	No Cirrhosis	Compensated Cirrhosis (Child-Pugh A)
1a	ZEP x 12 weeks ^a ZEP/RBV x 12 weeks [†] ZEP/RBV x 16 weeks [‡]	ZEP x 12 weeks ^a ZEP/RBV x 12 weeks [†] ZEP/RBV x 16 weeks [‡]
1b	ZEP x 12 weeks [§] ZEP/RBV x 12 weeks [†]	ZEP x 12 weeks [§] ZEP/RBV x 12 weeks [†]
4	ZEP/RBV x 16 weeks [§]	ZEP/RBV x 16 weeks [§]

^aPrior peginterferon alfa/ribavirin treatment without baseline NS5A polymorphisms at 28, 30, 31 or 93.

[†]Prior peginterferon alfa/ribavirin treatment with baseline NS5A polymorphisms at 28, 30, 31 or 93.

[‡]Prior Peginterferon alfa/ribavirin treatment.

[§]Prior Peginterferon alfa/ribavirin/HCV NS3/4A protease inhibitor.

Abbreviations: RBV, ribavirin; ZEP, Zepatier.

REFERENCES

1. Epclusa. Prescribing information. Gilead Sciences, Inc.; 2022. Accessed November 4, 2025. https://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/epclusa/epclusa_pi.pdf
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7. American Association for the Study of Liver Diseases – Infectious Diseases Society of America. Recommendations for testing, managing, and treating hepatitis C. Accessed November 4, 2025. <http://www.hcvguidelines.org>

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.