Generic Name: N/A

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

Preferred: N/A

Non-preferred: N/A

Date of Origin: 12/11/2023

Date Last Reviewed / Revised: 12/11/2023

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

PRIOR AUTHORIZATION CRITERIA

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

I. Diagnosis of chronic hepatitis C with quantitative baseline HCV-RNA testing.

II. Fibrosis assessment (e.g., FIB-4 score, FibroScan®, FibroSure®, liver biopsy, clinical evidence of cirrhosis).

III. Hepatitis C treatment history (if applicable).

IV. Hepatitis B surface antigen testing.

V. For HCV genotype 1a only: NS5A HCV resistance-associated substitution (RAS) testing

VI. Meets ALL criteria associated with the requested drug:

A. Epclusa® (sofosbuvir-velpatasvir)

i. Age 3 years and older.

ii. HCV genotypes 1, 2, 3, 4, 5, or 6.

iii. Contraindication to Mavyret (if no cirrhosis or compensated cirrhosis [Child-Pugh A]).

B. Harvoni® (ledipasvir-sofosbuvir)

i. Age 3 years and older.

ii. HCV genotypes 1, 4, 5, or 6

iii. Contraindication to either 1 or 2.

1. Mavyret® and Epclusa® in patients with no cirrhosis or compensated cirrhosis (Child-Pugh A).

2. Epclusa® in patients with decompensated cirrhosis (e.g., Child-Pugh B or C)

C. Mavyret (glecaprevir-pibrentasvir)

i. Age 3 years and older.

ii. HCV genotypes 1, 2, 3, 4, 5, or 6.

D. Sovaldi® (sofosbuvir)
    i. Age 3 to 17 years:
        1. Genotype 2 or 3 AND no cirrhosis or compensated cirrhosis.
    ii. Age 18 years and older:
        1. HCV genotypes 1, 2, 3 or 4 AND no cirrhosis or compensated cirrhosis (Child-Pugh A).
    iii. Contraindication to Epclusa® and Mavyret.

E. Vosevi® (sofosbuvir-velpatasvir-voxilaprevir)
    i. Age 18 years and older.
    ii. Treatment-experienced patients with HCV genotypes 1, 2, 3, 4, 5, or 6.
    iii. Contraindication, intolerance, or treatment failure with Mavyret®.

F. Zepatier® (elbasvir-grazoprevir)
    i. Age 12 years and older weighing at least 30 kg.
    ii. HCV genotype 1 or 4.
    iii. Contraindication to Mavyret.

VII. Medication is prescribed in accordance with FDA labeling and is supported by current clinical practice guidelines.

VIII. Treatment must be prescribed by or in consultation with a gastroenterologist, infectious disease specialist, or hepatologist.

IX. 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®.
    - Prior treatment with regimen containing BOTH an HCV NS5A inhibitor and a regimen containing an NS3/4A protease inhibitor (e.g., elbasvir/grazoprevir) in patients with chronic HCV genotype 1.

- 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).

- 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).
- 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 drugs contraindicated or not recommended in FDA labeling.

OTHER CRITERIA

- N/A

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
  - Age > 12 years OR weight > 45 kg: 84 tablets per 28 days.
  - Age 3 to < 12 years AND < 45 kg: 140 oral pellet packets per 28 days.
  - Age 3 to < 12 years AND weight > 45 kg: 84 tablets OR 168 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:** Reference tables in Appendix.
- **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 (No cirrhosis or compensated cirrhosis)**	**Post Liver Transplant (Decompensated)**
1a	EPC x 12 weeks	EPC x 12 weeks	RBV ineligible: EPC x 24 weeks RBV eligible: EPC/RBV x 12 weeks	EPC x 12 weeks	EPC/RBV x 12 weeks
1b	EPC x 12 weeks	EPC x 12 weeks	RBV ineligible: EPC x 24 weeks RBV eligible: EPC/RBV x 12 weeks	EPC x 12 weeks	EPC/RBV x 12 weeks
2	EPC x 12 weeks	EPC x 12 weeks	RBV ineligible: EPC x 24 weeks RBV eligible: EPC/RBV x 12 weeks	EPC x 12 weeks	EPC/RBV x 12 weeks
3	EPC x 12 weeks	(-) NS5RA RAS Y93H for VEL: EPC x 12 weeks (+) NS5RA RAS Y93H for VEL: EPC/RBV x 12 weeks	RBV ineligible: EPC x 24 weeks RBV eligible: EPC/RBV x 12 weeks	EPC x 12 weeks	EPC/RBV x 12 weeks
4	EPC x 12 weeks	EPC x 12 weeks	RBV ineligible: EPC x 24 weeks	EPC x 12 weeks	EPC/RBV x 12 weeks

			RBV eligible: EPC/RBV x 12 weeks		
5	EPC x 12 weeks	EPC x 12 weeks	RBV ineligible: EPC x 24 weeks RBV eligible: EPC/RBV x 12 weeks	EPC x 12 weeks	EPC/RBV x 12 weeks
6	EPC x 12 weeks	EPC x 12 weeks	RBV ineligible: EPC x 24 weeks RBV eligible: EPC/RBV x 12 weeks	EPC x 12 weeks	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 (No cirrhosis or compensated cirrhosis)**	**Post Liver Transplant (Decompensated)**
1a	EPC x 12 weeks[a]	EPC x 12 weeks[a]	EPC/RBV x 12 weeks[a] EPC/RBV x 24 weeks[b]	EPC x 12 weeks	EPC/RBV x 24 weeks
1b	EPC x 12 weeks[a]	EPC x 12 weeks[a]	EPC/RBV x 12 weeks[a] EPC/RBV x 24 weeks[b]	EPC x 12 weeks	EPC/RBV x 24 weeks
2	EPC x 12 weeks[a]	EPC x 12 weeks[a]	EPC/RBV x 12 weeks[a] EPC/RBV x 24 weeks[b]	EPC x 12 weeks	EPC/RBV x 24 weeks
3	EPC x 12 weeks[a]	EPC x 12 weeks[a]	EPC/RBV x 12 weeks[a] EPC/RBV x 24 weeks[b]	EPC x 12 weeks	EPC/RBV x 24 weeks
4	EPC x 12 weeks[a]	EPC x 12 weeks[a]	EPC/RBV x 12 weeks[a] EPC/RBV x 24 weeks[b]	EPC x 12 weeks	EPC/RBV x 24 weeks
5	EPC x 12 weeks[a]	EPC x 12 weeks[a]	EPC/RBV x 12 weeks[a] EPC/RBV x 24 weeks[b]	EPC x 12 weeks	EPC/RBV x 24 weeks
6	EPC x 12 weeks[a]	EPC x 12 weeks[a]	EPC/RBV x 12 weeks[a] EPC/RBV x 24 weeks[b]	EPC x 12 weeks	EPC/RBV x 24 weeks

[a]Prior treatment with peginterferon alfa/ribavirin with or without an HCV NS3/4A protease inhibitor (boceprevir, simeprevir, or telaprevir).
[b]Prior 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 (No cirrhosis or compensated cirrhosis)**	**Post Liver Transplant (Decompensated)**
1a	HIV (-) & HCV-RNA level < 6 million IU/mL: HAR x 8 weeks	HAR x 12 weeks	RBV ineligible: HAR x 24 weeks	HAR x 12 weeks[e] OR HAR/RBV x 12 weeks[f]	HAR/RBV x 12 weeks

	All others: HAR x 12 weeks		RBV eligible: HAR/RBV x 12 weeks		
1b	HIV (-) & HCV -RNA level < 6 million IU/mL: HAR x 8 weeks	HAR x 12 weeks	RBV ineligible: HAR x 24 weeks	HAR x 12 weeks[e] OR HAR/RBV x 12 weeks[f]	HAR/RBV x 12 weeks
	All others: HAR x 12 weeks		RBV eligible: HAR/RBV x 12 weeks		
4	HCV -RNA level < 6 million IU/mL without G4r: HAR x 8 weeks	HAR x 12 weeks	RBV ineligible: HAR x 24 weeks	HAR x 12 weeks[e] OR HAR/RBV x 12 weeks[f]	HAR/RBV x 12 weeks
	All others: HAR x 12 weeks		RBV eligible: HAR/RBV x 12 weeks		
5	HAR x 12 weeks	HAR x 12 weeks	RBV ineligible: HAR x 24 weeks	HAR x 12 weeks	HAR/RBV x 12 weeks
			RBV eligible: HAR/RBV x 12 weeks		
6	HAR x 12 weeks[c]	HAR x 12 weeks[c]	RBV ineligible: HAR x 24 weeks	HAR x 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 (No cirrhosis or compensated cirrhosis)**	**Post Liver Transplant (Decompensated)**
1a	HAR x 12 weeks	HAR x 24 weeks	RBV ineligible: HAR x 24 weeks	HAR x 12 weeks[e] OR HAR/RBV x 12 weeks[f]	HAR/RBV x 24 weeks[e]
			RBV eligible: HAR/RBV x 12 weeks HAR/RBV x 24 weeks[d]		
1b	HAR x 12 weeks	HAR x 24 weeks	RBV ineligible: HAR x 24 weeks	HAR x 12 weeks[e] OR HAR/RBV x 12 weeks[f]	HAR/RBV x 24 weeks[e]
			RBV eligible: HAR/RBV x 12 weeks HAR/RBV x 24 weeks[d]		
4	HAR x 12 weeks	HAR x 12 weeks	RBV ineligible: HAR x 24 weeks	HAR x 12 weeks[e] OR HAR/RBV x 12 weeks[f]	HAR/RBV x 24 weeks[e]
			RBV eligible: HAR/RBV x 12 weeks HAR/RBV x 24 weeks[d,]		
5	HAR x 12 weeks[c]	HAR x 12 weeks[c]	RBV ineligible: HAR x 24 weeks	HAR x 12 weeks[e]	HAR/RBV x 24 weeks[e]
			RBV eligible: HAR/RBV x 12 weeks HAR/RBV x 24 weeks[d]		
6	HAR x 12 weeks[c]	HAR x 12 weeks[c]	RBV ineligible: HAR x 24 weeks	HAR x 12 weeks[e]	HAR/RBV x 24 weeks[e]
			RBV eligible: HAR/RBV x 12 weeks HAR/RBV x 24 weeks[d]		

[c]Not recommended for genotype 6e subtype.
[d]Prior sofosbuvir- or NS5A inhibitor-based treatment failure.
[e]Recommendation from the American Association for the Study of Liver Diseases – Infectious Diseases Society of America. Recommendations for testing, managing, and treating hepatitis C Guidance.

[f]Recommendation 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 Naive			
Genotype	**No Cirrhosis**	**Compensated Cirrhosis (Child-Pugh A)**	**Post Liver Transplant (No cirrhosis or compensated cirrhosis)**
1a	MAV x 8 weeks	MAV x 8 weeks	MAV x 12 weeks
1b	MAV x 8 weeks	MAV x 8 weeks	MAV x 12 weeks
2	MAV x 8 weeks	MAV x 8 weeks	MAV x 12 weeks
3	MAV x 8 weeks	MAV x 8 weeks	MAV x 12 weeks
4	MAV x 8 weeks	MAV x 8 weeks	MAV x 12 weeks
5	MAV x 8 weeks	MAV x 8 weeks	MAV x 12 weeks
6	MAV x 8 weeks[g]	MAV x 8 weeks[g]	MAV x 12 weeks
Treatment Experienced			
1a	MAV x 8 weeks[h] MAV x 12 weeks[i] MAV X 16 weeks[j]	MAV x 12 weeks[h,i] MAV X 16 weeks[j]	MAV x 12 weeks
1b	MAV x 8 weeks[h] MAV x 12 weeks[i] MAV X 16 weeks[j]	MAV x 12 weeks[h,i] MAV X 16 weeks[j]	MAV x 12 weeks
2	MAV x 8 weeks[h]	MAV x 12 weeks[h]	MAV x 12 weeks
3	MAV x 16 weeks[h]	MAV x 16 weeks[h]	MAV x 12 weeks
4	MAV x 8 weeks[h]	MAV x 12 weeks[h]	MAV x 12 weeks
5	MAV x 8 weeks[h]	MAV x 12 weeks[h]	MAV x 12 weeks
6	MAV x 8 weeks[h]	MAV x 12 weeks[h]	MAV x 12 weeks

[g]Not recommended for genotype 6e subtype.
[h]Prior treatment regimens containing peginterferon, ribavirin, and/or sofosbuvir, but no HCV NS3/4A protease inhibitor or NS5A inhibitor.
[i]Prior NS3/4A protease inhibitor treatment without an NS5A inhibitor (i.e., simeprevir and sofosbuvir, or simeprevir, boceprevir, or telaprevir with peginterferon and ribavirin).
[j]Prior NS5A inhibitor treatment without an NS3/4A protease inhibitor (i.e., ledipasvir and sofosbuvir or daclatasvir with peginterferon and ribavirin).
Abbreviations: MAV, Mavyret®.

Table 4. Sovaldi® Treatment Recommendations and Approval Length

Treatment Naive			
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)

[k]Failure 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)**
1a	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]
1b	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]
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 eligibile: VOS/RBV x 12 weeks[n]
4	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]
5	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]
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]

[l]Prior treatment with NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir).
[m]Prior treatment sofosbuvir with or without peginterferon alfa/ribavirin, ribavirin, or HCV NS3/4A protease inhibitor (boceprevir, simeprevir, or telaprevir.
[n]Prior treatment with sofosbuvir/velpatasvir and baseline NS5A RAS Y93H for velatpatasvir.
[o]Prior treatment with glecaprevir/pibrentasvir
[p]Prior multiple direct acting antivirals treatment failure, including sofosbuvir plus glecaprevir/pibrentasivir
Abbreviations: RBV, ribavirin; VOS, Vosevi®.

Table 6. Zepatier® Treatment Recommendations and Approval Length

Genotype	**No Cirrhosis**	**Compensated Cirrhosis (Child-Pugh A)**
1a	ZEP x 12 weeks	ZEP x 12 weeks
1b	ZEP x 12 weeks	ZEP x 12 weeks
4	ZEP x 12 weeks	ZEP x 12 weeks
Genotype	**No Cirrhosis**	**Compensated Cirrhosis (Child-Pugh A)**
1a	ZEP x 12 weeks[q] ZEP/RBV x 12 weeks[t] ZEP/RBV x 16 weeks[r]	ZEP x 12 weeks[q] ZEP/RBV x 12 weeks[t] ZEP/RBV x 16 weeks[r]
1b	ZEP x 12 weeks[s] ZEP/RBV x 12 weeks[t]	ZEP x 12 weeks[s] ZEP/RBV x 12 weeks[t]
4	ZEP/RBV x 16 weeks[s]	ZEP/RBV x 16 weeks[s]

[q]Prior peginterferon alfa/ribavirin treatment without baseline NS5A polymorphisms at 28, 30, 31 or 93.
[r]Prior peginterferon alfa/ribavirin treatment with baseline NS5A polymorphisms at 28, 30, 31 or 93.
[s]Prior Peginterferon alfa/ribavirin treatment.
[t]Prior Peginterferon alfa/ribavirin/HCV NS3/4A protease inhibitor.

Abbreviations: RBV, ribavirin; ZEP, Zepatier®.

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