

Hepatitis C Direct Acting Antivirals Prior Authorization with Quantity Limit – Through Preferred Agents Program Summary

Hepatitis C Direct Acting Antivirals Prior Authorization with Quantity Limit– Through Preferred Oral Agent(s)

OBJECTIVE

The intent of the Hepatitis C Second Generation Antivirals Prior Authorization (PA) program is to appropriately select patients for therapy according to the Food and Drug Administration (FDA) approved product labeling and/or clinical guidelines and/or clinical studies. The PA process will consider treatment guideline recommendations with supporting clinical evidence of Class IIa, Level C or better that are recommended regimens and not alternatives, however FDA labeled indications for products new to market may be used to supplement national guideline recommendations where guidance is limited or outdated. The criteria will allow for patients requesting a preferred regimen. A preferred agent may be approved for use once all criteria have been met; a non-preferred agent may be approved if the patient is currently treated with the non-preferred agent.

TARGET AGENT(S)

Preferred and Non-Preferred Agents as determined by client^a

Genotype	Preferred Agent(s)	Non-Preferred Agent(s)
1	Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Sovaldi (sofosbuvir) ^b Viekira PAK (ombitasvir/paritaprevir/ritonavir + dasabuvir) Zepatier (elbasvir/grazoprevir)
2	Epclusa (sofosbuvir/velpatasvir) Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Sovaldi (sofosbuvir) ^b
3	Epclusa (sofosbuvir/velpatasvir) Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Sovaldi (sofosbuvir) ^b
4	Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	Sovaldi (sofosbuvir) ^b Zepatier (elbasvir/grazoprevir)
5	Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir	

	Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	
6	Epclusa (sofosbuvir/velpatasvir) Harvoni (ledipasvir/sofosbuvir) Ledipasvir/Sofosbuvir Sofosbuvir/Velpatasvir Mavyret (glecaprevir/pibrentasvir) Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	

^aPreferred agents will require prior authorization. The prior authorization for a specific agent will be based the Food and Drug Administration (FDA) approved product labeling for the patient's specific factors (e.g., age and/or weight, genotype, cirrhosis status, treatment naïve vs. experienced, previous treatment)

^bSovaldi is non-preferred for patients without hepatocellular carcinoma. Exceptions made for patients with genotypes 2 or 3 who are at least 3 years of age to under 6 years of age and < 17 kg.

Brand (generic)	GPI	Multisource Code	Quantity Limit
Epclusa® (sofosbuvir/velpatasvir)			
150 mg sofosbuvir/37.5 mg velpatasvir packet with oral pellets	12359902653020	M, N, O, or Y	1 packet
200 mg sofosbuvir/50 mg packet with oral pellets	12359902653030	M, N, O, or Y	1 packet
200 mg sofosbuvir/50 mg velpatasvir tablets	12359902650320	M, N, O, or Y	1 tablet/day
400 mg sofosbuvir/100 mg velpatasvir tablets	12359902650330	M, N, O, or Y	1 tablet/day
Harvoni® (ledipasvir/sofosbuvir)			
33.75 mg/150 mg packet with oral pellets	12359902403006	M, N, O, or Y	1 packet/day
45 mg/200 mg tablets	12359902400310	M, N, O, or Y	1 tablet/day
45 mg/200 mg packet with oral pellets	12359902403010	M, N, O, or Y	1 packet/day
90 mg ledipasvir/ 400 mg sofosbuvir tablets	12359902400320	M, N, O, or Y	1 tablet/day
Ledipasvir / sofosbuvir			
90 mg ledipasvir/ 400 mg sofosbuvir tablets	12359902400320	M, N, O, or Y	1 tablet/day
Mavyret™ (glecaprevir/pibrentasvir)			
50 mg glecaprevir/20 mg pibrentasvir	12359902353020	M, N, O, or Y	5 packets
100 mg glecaprevir/40 mg pibrentasvir tablets	12359902350320	M, N, O, or Y	3 tablets/day
Sofosbuvir/velpatasvir			
400 mg sofosbuvir/ 100 mg velpatasvir tablets	12359902650330	M, N, O, or Y	1 tablet/day
Sovaldi® (sofosbuvir)			
150 mg packet with oral pellets	12353080003015	M, N, O, or Y	1 packet/day
200 mg tablets	12353080000310	M, N, O, or Y	1 tablet/day
200 mg packet with oral pellets	12353080003020	M, N, O, or Y	1 packet/day
400 mg tablets	12353080000320	M, N, O or Y	1 tablet/day
Viekira PAK™ (ombitasvir/paritaprevir/ritonavir + dasabuvir)			
12.5/75/50 mg ombitasvir/ paritaprevir/ritonavir + 250 mg dasabuvir tablets	1235990460B720	M, N, O or Y	1 pack (112 tablets)/28 days
Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)			

400 mg sofosbuvir/100 mg velpatasvir/100 mg voxilaprevir tablets	12359903800330	M, N, O, or Y	1 tablet/day
Zepatier® (elbasvir/grazoprevir)			
50 mg elbasvir/100 mg grazoprevir tablets	12359902300320	M, N, O, or Y	1 tablet/day

New to Market Hepatitis C Target Agents (This section will be populated when there are new recently FDA approved hepatitis C agents)

Requested agent/regimen	Genotype	Preferred agent(s)*

*Offer only those preferred agents that are indicated for the patient's specific factors (e.g., age and/or weight, genotype, cirrhosis status, treatment naïve vs. experienced, previous treatment)

Brand (generic)	GPI	Multisource Code	Quantity Limit

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Epclusa and Sofosbuvir/Velpatasvir Evaluation

Epclusa or Sofosbuvir/Velpatasvir will be approved when ALL of the following are met:

1. The patient has a diagnosis of hepatitis C genotype 1, 2, 3, 4, 5, or 6
AND
2. ONE of the following:
 - A. The patient is treatment naïve
OR
 - B. The patient was previously treated (i.e. treatment experienced) with ONLY peg-interferon and ribavirin with or without an HCV protease inhibitor
OR
 - C. The patient has decompensated cirrhosis
- AND**
3. ONE of the following:
 - A. The patient's age is within FDA labeling for the requested indication for the requested agent
OR
 - B. The patient's weight is within FDA labeling for the requested indication for the requested agent
OR
 - C. The prescriber has provided information supporting the use of the requested agent for the patient's age AND weight (medical records required)
- AND**
4. The prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection
AND
5. If the screening for HBV was positive for current or prior HBV infection, the prescriber will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent
AND
6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist, or infectious disease) or has consulted with a specialist in the area of the patient's diagnosis
AND
7. The patient does NOT have any FDA labeled contraindications to the requested agent
AND
8. The patient meets all requirements and will use the requested agent in a treatment regimen noted in Tables 1, 1a or 2
AND
9. The requested length of therapy does NOT exceed the length of therapy noted in Tables 1, 1a or 2 for the patient's regimen
AND

10. ONE of the following:

A. The requested quantity (dose) does NOT exceed the program quantity limit

OR

B. The requested quantity (dose) exceeds the program quantity limit AND ALL of the following:

i. The requested agent is Epclusa 200 mg/50 mg tablet

AND

ii. The requested quantity (dose) does NOT exceed 2 tablets per day

AND

iii. The prescriber has provided information supporting why the patient cannot take 1 tablet of the 400 mg/100mg tablet

Length of approval:

For BCBSIL members: approve for 6 months

For all other plans: Up to the duration of treatment as determined in Tables 1, 1a or 2

Table 1: Epclusa or Sofosbuvir/Velpatasvir Treatment Recommendations based on FDA labeling

Genotype	Patient population*	Treatment	Duration	Number of Fills	Duration of PA Detailing
1, 2, 3, 4, 5, or 6	Patients without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh A)	Epclusa	12 weeks	3	16
	Patients with decompensated cirrhosis (Child-Turcotte-Pugh B and C)	Epclusa + ribavirin	12 weeks	3	16

* HCV/HIV-1 co-infection: For patients with HCV/HIV-1 co-infection, follow the Epclusa dosage recommendations in the table above

Table 1a: Epclusa Treatment Recommendations based on AASLD Guidelines Class IIa, Level C or better

Genotype	Patient population	Treatment	Duration	Number of Fills	Duration of PA Detailing
1, 2, 3, 4, 5, or 6	Hepatocellular carcinoma	Epclusa + ribavirin	12 weeks (24 weeks if rbv-ineligible)	3 (6)	16 weeks (28 weeks)

Table 2: Epclusa or sofosbuvir/Velpatasvir Decompensated Cirrhosis Treatment Recommendations based on AASLD/IDSA Guidelines for unique populations

Genotype	Patient population ^e	Treatment	Duration
1, 2, 3, 4, 5, or 6	Patients with decompensated cirrhosis (Child-Turcotte-Pugh B and C) who are ribavirin ineligible ^h	Epclusa	24 weeks
1, 2, 3, 4, 5, or 6	Patients with decompensated cirrhosis (Child-Turcotte-Pugh B and C) in whom prior sofosbuvir- or NS5A inhibitor-based treatment failed ^j	Epclusa with weight-based ribavirin (low initial dose of ribavirin (600 mg) is recommended for patients with Child-Turcotte-Pugh class C cirrhosis)	24 weeks

e - HCV/HIV-1 co-infection, follow recommendations in table above

Harvoni and Ledipasvir/Sofosbuvir Evaluation

Harvoni or Ledipasvir/Sofosbuvir will be approved when ALL of the following are met:

1. The patient has a diagnosis of hepatitis C genotype 1, 4, 5, or 6
AND
2. The prescriber has provided the patient's baseline HCV RNA level if the patient has genotype 1
AND
3. ONE of the following:
 - A. The patient is treatment naïve
OR
 - B. The patient was previously treated (i.e. treatment experienced) with peg-interferon and ribavirin with or without an HCV protease inhibitor
OR
 - C. The patient has decompensated cirrhosis**AND**
4. The prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection
AND
5. If the screening for HBV was positive for current or prior HBV infection, the prescriber will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent
AND
6. ONE of the following:
 - A. The patient's age is within FDA labeling for the requested indication for the requested agent
OR
 - B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication**AND**
7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist, or infectious disease) or has consulted with a specialist in the area of the patient's diagnosis
AND
8. The patient does NOT have any FDA labeled contraindications to the requested agent
AND
9. The patient meets all requirements and will use the requested agent in a treatment regimen noted in Tables 3, 4 or 4a
AND
10. The requested length of therapy does NOT exceed the length of therapy noted in Table 3, 4 or 4a for the patient's treatment regimen
AND
11. ONE of the following:
 - A. The requested quantity (dose) does NOT exceed the program quantity limit
OR
 - B. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following:
 - i. The requested agent is Harvoni 45 mg/200 mg oral pellets AND BOTH of the following:
 1. The requested quantity (dose) does NOT exceed 2 packets daily
AND
 2. The prescriber has provided information stating why the patient cannot take 1 tablet of Harvoni 90 mg/400 mg strength**OR**
 - ii. The requested agent is Harvoni 45 mg/200 mg tablet AND BOTH of the following:
 1. The requested quantity (dose) does NOT exceed 2 tablets daily
AND
 2. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

Length of approval:

For BCBSIL members: approve for 6 months

For all other plans: Up to the duration of treatment as determined in Tables 3, 4, or 4a.

Table 3: Harvoni or Ledipasvir/Sofosbuvir Treatment Recommendations based on FDA labeling

Genotype	Patients 3 years of age and older ^e	Treatment	Treatment Duration	Number of Fills	Duration of PA detailing
1	Treatment-naïve with initial viral load of < 6 M IU/mL and without cirrhosis, HIV infection, history of liver transplantation and/or are not black or African-American	Harvoni	For BCBSMT and BCBSNM: 12 weeks	3	16
			For all other plans: 8 weeks * Note approve 8 weeks length of therapy only if prescriber is requesting 8 weeks of therapy.	2	12
	Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh A)	Harvoni	12 weeks	3	16
	Treatment-experienced ^g without cirrhosis	Harvoni	12 weeks	3	16
	Treatment-experienced ^g with compensated cirrhosis (Child-Turcotte-Pugh A) and eligible for ribavirin	Harvoni + ribavirin	12 weeks	3	16
	Treatment-experienced ^g with compensated cirrhosis (Child-Turcotte-Pugh A) and ineligible for ribavirin ^h	Harvoni	24 weeks	6	28
	Treatment-naïve and treatment-experienced ^g with decompensated cirrhosis (Child-Turcotte-Pugh B or C)	Harvoni + ribavirin	12 weeks	3	16
1 or 4	Treatment-naïve and treatment-experienced ^g liver transplant recipients without cirrhosis, or with compensated cirrhosis (Child-Turcotte-Pugh A)	Harvoni + ribavirin	12 weeks	3	16
4, 5, or 6	Treatment-naïve and treatment-experienced ^g without cirrhosis or with	Harvoni	12 weeks	3	16

	compensated cirrhosis (Child-Turcotte-Pugh A)				
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e - HCV/HIV-1 co-infection, follow recommendation in table above

g - Treatment-experienced - patients who have failed therapy with either peg-interferon + ribavirin ± an HCV protease inhibitor [e.g., boceprevir, paritaprevir, simeprevir, telaprevir].

h - Ribavirin ineligible - patients with history of intolerance, contraindication, or hypersensitivity to ribavirin

Table 4: Harvoni or Ledipasvir/Sofosbuvir Decompensated Cirrhosis Treatment Recommendations based on AASLD Guidelines for unique populations

Genotype	Patient's 3 years of age and older ^e	Treatment	Treatment Duration
1, 4, 5, or 6	Patients with decompensated cirrhosis (Child-Turcotte-Pugh B or C) AND are ribavirin ineligible ^h	Harvoni	24 weeks
1, 4, 5, or 6	Patients with decompensated cirrhosis (Child-Turcotte-Pugh B or C) previously treated with sofosbuvir-based treatment failure	Harvoni + low initial dose of ribavirin (600 mg); increase as tolerated)	24 weeks

e - HCV/HIV-1 co-infection, follow recommendations in table above

h - Ribavirin ineligible - patients with history of intolerance, contraindication, or hypersensitivity to ribavirin

Table 4a Harvoni or Ledipasvir/sofosbuvir Treatment Recommendations based on AASLD guidelines Class IIa, Level C or Better

Genotype	Adult Patient Population	Treatment	Treatment Duration	Number of Fills	Duration of PA detailing
1, 4, 5, or 6	Treatment-naïve and treatment-experienced** kidney transplant patients with or without compensated cirrhosis (Child-Turcotte-Pugh A)	Harvoni	12 weeks	3	16 weeks
1, 4, 5, or 6	Decompensated cirrhosis (Child-Turcotte-Pugh B or C) including those with hepatocellular carcinoma	Harvoni+RBV	12 weeks [24 weeks if RBV-ineligible]	3 [6]	16 weeks [28 weeks]
	Decompensated cirrhosis (Child-Turcotte-Pugh B or C) including those with hepatocellular carcinoma in whom prior sofosbuvir-based treatment failed	Harvoni+RBV	24 weeks	6	28 weeks

**Treatment-experienced - patients who have failed therapy with either peg-interferon + ribavirin or a HCV protease inhibitor + peginterferon + ribavirin.

Mavyret Evaluation

Mavyret will be approved when ALL of the following are met:

1. The patient has a diagnosis of hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2. ONE of the following:

A. The patient's age is within FDA labeling for the requested indication for the requested agent

OR

B. The patient's weight is within FDA labeling for the requested indication for the requested agent

OR

C. The prescriber has provided information supporting the use of the requested agent for the patient's age AND weight (medical records required)

AND

3. The prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection

AND

4. If the screening for HBV was positive for current or prior HBV infection, the prescriber will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent

AND

5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist, or infectious disease) or has consulted with a specialist in the area of the patient's diagnosis

AND

6. The patient has not been previously treated with the requested agent

AND

7. The patient does NOT have any FDA labeled contraindications to the requested agent

AND

8. The patient meets all requirements and will use the requested agent in a treatment regimen noted in Table 5 (FDA labeling)

AND

9. The requested length of therapy does NOT exceed the length of therapy noted in Table 5 (FDA labeling) for the patient's treatment regimen

AND

10. The requested quantity (dose) does NOT exceed the program quantity limit

Length of approval:

For BCBSIL members: approve for 6 months

For all other plans: Up to the duration of treatment as determined in Table 5

Table 5: Mavyret Treatment Recommendations based on FDA labeling

Genotype	Patient Population - adults and pediatric patients 12 years of age or older or weighing at least 45 kg*	Treatment	Treatment Duration		Number of Fills	Duration of PA detailing
			No Cirrhosis	Compensated Cirrhosis (Child-Turcotte-Pugh A)		
1, 2, 3, 4, 5, or 6	Liver or kidney transplant recipients	Mavyret	12 weeks	12 weeks	3	16
1	Liver or kidney transplant recipients who are treatment experienced with an NS5A inhibitor ¹ but without prior treatment with an NS3/4A	Mavyret	16 weeks	16 weeks	4	20

	protease inhibitor (PI)					
3	Liver or kidney transplant recipients who are treatment experienced with PRS ³	Mavyret	16 weeks	16 weeks	4	20
1, 2, 3, 4, 5, or 6	Treatment naïve	Mavyret	For BCBSMT and BCBSNM: 12 weeks	For BCBSMT and BCBSNM: 12 weeks	3	16
			For all other plans: 8 weeks	For all other plans: 8 weeks	2	12
1	Treatment experienced with an NS5A inhibitor ¹ but without prior treatment with an NS3/4A protease inhibitor (PI)	Mavyret	16 weeks	16 weeks	4	20
1	Treatment experienced with an NS3/4A protease inhibitor ² but without prior treatment with an NS5A inhibitor	Mavyret	12 weeks	12 weeks	3	16
1, 2, 4, 5, or 6	Treatment experienced with PRS ³	Mavyret	For BCBSMT and BCBSNM: 12 weeks For all other plans: 8 weeks	12 weeks	2 or 3 depending on cirrhosis	12 or 16 depending on cirrhosis
3	Treatment experienced with PRS ³	Mavyret	16 weeks	16 weeks	4	20

*Follow the dosage recommendations above for HCV/HIV co infected patient and in patients with any degree of kidney impairment (including those on hemodialysis)

1. Examples of HCV NS5A inhibitors include daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir.

2. Examples of NS3/4A protease inhibitors include simeprevir, boceprevir, telaprevir

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

Sovaldi Evaluation

Sovaldi will be approved when ALL of the following are met:

1. ONE of the following:

A. The patient is a pediatric patient with a diagnosis of hepatocellular carcinoma secondary to chronic hepatitis C genotype 2 or 3 AND ONE of the following:

i. The patient's age is within FDA labeling for the requested agent for the requested indication

OR

ii. The prescriber has provided information in support of using the requested agent for the patient's age

OR

B. The patient is a pediatric patient with a diagnosis of hepatitis C genotype 2 or 3 AND ALL of the following:

i. ONE of the following:

1. The patient's age is within FDA labeling for the requested agent for the requested indication

OR

2. The prescriber has provided information in support of using the requested agent for the patient's age

AND

ii. ONE of the following:

a. The patient is < 6 years of age AND weighs < 17 kg

OR

b. The patient is < 12 years of age AND weighs < 45 kg then ONE of the following:

i. The patient has an intolerance or hypersensitivity to Epclusa [chart notes are required]

OR

ii. The patient has an FDA labeled contraindication to Epclusa [chart notes are required]

OR

iii. Epclusa is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; **OR** cause a significant barrier to the patient's adherence of care; **OR** worsen a comorbid condition; **OR** decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; **OR** cause an adverse reaction or cause physical or mental harm [chart notes are required]

OR

iv. Epclusa is not in the best interest of the patient based on medical necessity [chart notes are required]

OR

v. The prescriber has provided information supporting the use of the requested agent over Epclusa (e.g., the patient is currently taking the requested agent)

OR

c. The patient is currently being treated with the non-preferred agent and the patient is currently stable on the non-preferred agent [chart notes are required]

OR

d. The patient has an intolerance or hypersensitivity to BOTH Epclusa and Mavyret [chart notes are required]

OR

e. The patient has an FDA labeled contraindication to BOTH Epclusa and Mavyret [chart notes are required]

OR

f. BOTH Epclusa and Mavyret are expected to be ineffective based on the known clinical characteristics of the patient and the known

characteristics of the prescription drug; **OR** cause a significant barrier to the patient's adherence of care; **OR** worsen a comorbid condition; **OR** decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; **OR** cause an adverse reaction or cause physical or mental harm [chart notes are required]

OR

- g. BOTH Epclusa and Mavyret are not in the best interest of the patient based on medical necessity [chart notes are required]

OR

- h. The prescriber has provided information supporting the use of the requested agent over BOTH Epclusa and Mavyret (e.g., the patient is currently taking the requested agent)

AND

- iii. ONE of the following:

- 1. The patient is treatment naïve

OR

- 2. The patient was previously treated (i.e. treatment experienced) with ONLY peg-interferon and ribavirin

OR

- C. The patient is an adult and has a diagnosis of hepatocellular carcinoma secondary to chronic hepatitis C genotype 1, 2, 3, or 4

OR

- D. The patient is an adult with a diagnosis of hepatitis C genotype 1, 2, 3, or 4 AND BOTH of the following:

- i. ONE of the following:

- 1. The patient is treatment naïve

OR

- 2. The patient was previously treated (i.e. treatment experienced) with ONLY peg-interferon and ribavirin

AND

- ii. ONE of the following:

- 1. The patient is currently being treated with the non-preferred agent and the patient is currently stable on the non-preferred agent [chart notes are required]

OR

- 2. The patient has an intolerance or hypersensitivity to ALL preferred agent(s) for the patient's specific factors (e.g., age and/or weight, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment) [chart notes are required]

OR

- 3. The patient has an FDA labeled contraindication to ALL preferred agent(s) for the patient's specific factors (e.g., age and/or weight, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment) [chart notes are required]

OR

- 4. The preferred agent(s) for the patient's specific factors (e.g., age and/or weight, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment) is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; **OR** cause a significant barrier to the patient's adherence of care; **OR** worsen a comorbid condition; **OR** decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; **OR** cause an adverse reaction or cause physical or mental harm [chart notes are required]

OR

- 5. The preferred agent(s) for the patient's specific factors (e.g., age and/or weight, genotype, cirrhosis status, treatment naïve vs treatment experienced,

previous treatment) is not in the best interest of the patient based on medical necessity [chart notes are required]

OR

6. The prescriber has provided information supporting the use of the non-preferred agent over the preferred agent(s) (e.g., patient is currently taking the requested agent)

AND

2. The prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection

AND

3. If the HBV screening was positive for current or prior HBV infection, the prescriber will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent

AND

4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist, infectious disease) or has consulted with a specialist in the area of the patient's diagnosis

AND

5. The patient does NOT have any FDA labeled contraindications to the requested agent

AND

6. The patient meets all requirements and will use the requested agent in a treatment regimen noted in Table 6 or 7

AND

7. The requested length of therapy does NOT exceed the length of therapy noted in Table 6 or 7 for the patient's treatment regimen

AND

8. ONE of the following:

- A. The requested quantity (dose) does NOT exceed the program quantity limit

OR

- B. The requested agent is Sovaldi 200 mg oral pellets AND BOTH of the following:

- i. The requested quantity (dose) does NOT exceed 2 packets daily

AND

- ii. The prescriber has provided information stating why the patient cannot take 1 tablet of Sovaldi 400 mg strength

OR

- C. The requested agent is Sovaldi 200 mg tablets AND BOTH of the following:

- i. The requested quantity (dose) does NOT exceed 2 tablets daily

AND

- ii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

Length of approval:

For BCBSIL members: approve for 6 months OR up to duration of treatment as determined in Table 6 or 7, whichever is longer

For all other plans: Up to the duration of treatment as determined in Table 6 or 7

Table 6: Sovaldi Treatment Recommendations in Adult Patients with Genotype 1, 2, 3, or 4 Based on FDA Labeling

Patient population*	Treatment	Duration of therapy
Genotype 1 or 4 treatment naïve without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh A)	Sovaldi + Peg-interferon alfa + ribavirin	12 weeks
Genotype 1 treatment naïve without cirrhosis or with compensated cirrhosis (Child-	Sovaldi + ribavirin	24 weeks

Turcotte-Pugh A) (interferon ineligible [±])		
Genotype 2 treatment naïve or treatment experienced [‡] without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh A)	Sovaldi + ribavirin	12 weeks
Genotype 3 treatment naïve or treatment experienced [‡] without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh A)	Sovaldi + ribavirin	24 weeks
1-4 with hepatocellular carcinoma awaiting liver transplantation	Sovaldi + ribavirin	Up to 48 weeks

*HCV/HIV-1 co-infection, follow recommendations in table above

[±]Interferon ineligible is defined as one or more of the following:

- Intolerance to interferon
- Autoimmune hepatitis and other autoimmune disorders
- Hypersensitivity to PEG interferon or any of its components
- Decompensated hepatic disease
- Major uncontrolled depressive illness
- A baseline neutrophil count below 1500/ μ L
- A baseline platelet count below 90,000/ μ L
- A baseline hemoglobin below 10 g/dL
- A history of preexisting cardiac disease

[‡]Treatment experienced patients who have failed an interferon based regimen with or without ribavirin

Table 7: Sovaldi and Ribavirin with or without Peg-interferon Treatment Recommendations for Pediatric Patients 3 Years of Age and Older Based on FDA Labeling

Genotype	Pediatric Patient population	Treatment	Duration of therapy
2	Treatment-naïve and treatment experienced [‡] without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh A)	Sovaldi + ribavirin	12 weeks
3	Treatment-naïve and treatment experienced [‡] without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh A)	Sovaldi + ribavirin	24 weeks
2 or 3	Pediatric patients with hepatocellular carcinoma awaiting liver transplantation	Sovaldi + ribavirin	48 weeks

[‡]Treatment experienced patients who have failed an interferon based regimen with or without ribavirin

Viekira Pak Evaluation

Viekira PAK will be approved when ALL of the following are met:

1. The patient has a diagnosis of hepatitis C genotype 1
AND
2. The prescriber has provided the patient's subtype
AND
3. ONE of the following:
 - A. The patient is treatment naïve
OR
 - B. The patient was previously treated (i.e. treatment experienced) with ONLY peg-interferon and ribavirin**AND**
4. ONE of the following:
 - A. The patient's age is within FDA labeling for the requested indication for the requested agent

OR

- B. The prescriber has provided information supporting the use of the requested agent for the patient's age

AND

5. The prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection

AND

6. If the HBV screening was positive for current or prior HBV infection, the prescriber will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent

AND

7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist, or infectious disease) or has consulted with a specialist in the area of the patient's diagnosis

AND

8. ONE of the following:

- A. The patient is currently being treated with the non-preferred agent and the patient is currently stable on the non-preferred agent [chart notes are required]

OR

- B. The patient has an intolerance or hypersensitivity to ALL preferred agent(s) for the patient's specific factors (e.g., age and/or weight, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment) [chart notes are required]

OR

- C. The patient has an FDA labeled contraindication to ALL preferred agent(s) for the patient's specific factors (e.g., age and/or weight, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment) [chart notes are required]

OR

- D. The preferred agent(s) for the patient's specific factors (e.g., age and/or weight, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment) is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; **OR** cause a significant barrier to the patient's adherence of care; **OR** worsen a comorbid condition; **OR** decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; **OR** cause an adverse reaction or cause physical or mental harm [chart notes are required]

OR

- E. The preferred agent(s) for the patient's specific factors (e.g., age and/or weight, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment) is not in the best interest of the patient based on medical necessity [chart notes are required]

OR

- F. The prescriber has provided information supporting the use of the non-preferred agent over the preferred agent(s) (e.g., patient is currently taking the requested agent)

AND

9. The patient does NOT have any FDA contraindications to the requested agent

AND

10. The patient meets all requirements and will use the requested agent in a treatment regimen noted in Table 8 (FDA labeling)

AND

11. The requested length of therapy does NOT exceed the length of therapy noted in Table 8 (FDA labeling) for the patient's treatment regimen

AND

12. The requested quantity (dose) does NOT exceed the program quantity limit

Length of approval:

For BCBSIL members: approve for 6 months

For all other plans: Up to the duration as determined in Table 8

Table 8: Viekira PAK Treatment Recommendations based on FDA labeling

Patient Population	Treatment*	Duration
Genotype 1a, without cirrhosis	Viekira PAK + ribavirin	12 weeks

Genotype 1a, with compensated cirrhosis	Viekira PAK + ribavirin	24 weeks
Genotype 1b, with or without compensated cirrhosis	Viekira PAK	12 weeks
Genotype 1a or 1b post liver transplant with normal hepatic function (i.e. Metavir ≤ 2)	Viekira PAK + ribavirin	24 weeks

*HCV/HIV-1 co-infection, follow recommendations in table above

Vosevi Evaluation

Vosevi will be approved when ALL of the following are met:

1. The patient has a diagnosis of hepatitis C genotype 1, 2, 3, 4, 5, or 6
AND
2. If genotype 1, the prescriber has provided the patient's subtype
AND
3. The patient is NOT treatment naïve
AND
4. The patient has NOT been previously treated with the requested agent
AND
5. ONE of the following:
 - A. The patient's age is within FDA labeling for the requested indication for the requested agent
OR
 - B. The prescriber has provided information supporting the use of the requested agent for the patient's age
- AND**
6. The prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection
AND
7. If the screening for HBV was positive for current or prior HBV infection, the prescriber will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent
AND
8. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist, or infectious disease) or has consulted with a specialist in the area of the patient's diagnosis
AND
9. The patient does NOT have any FDA labeled contraindications to the requested agent
AND
10. The patient meets all requirements and will use the requested agent in a treatment regimen noted in Table 9
AND
11. The requested length of therapy does NOT exceed the length of therapy noted in Table 9 for the patient's treatment regimen
AND
12. The requested quantity (dose) does NOT exceed the program quantity limit

Length of approval:

For BCBSIL members: approve for 6 months

For all other plans: Up to the duration of treatment as determined in Table 9

Table 9: Vosevi Treatment Recommendations based on FDA labeling

Patient Population	Patients Previously Treated with an HCV Regimen Containing:	Treatment Duration
Genotype 1,2,3,4,5, or 6 without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh A)	An NS5A inhibitor ^a	12 weeks

Genotype 1a or 3 without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh A)	Sofosbuvir without an NS5A inhibitor ^b	12 weeks
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a - Examples of HCV NS5A inhibitors include daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir

b - Sofosbuvir with or without any of the following: peginterferon alfa/ribavirin, ribavirin, HCV NS3/4A protease inhibitor (simeprevir)

Zepatier Evaluation

Zepatier will be approved when ALL of the following are met:

1. The patient has a diagnosis of hepatitis C genotype 1 or 4
AND
2. BOTH of the following:
 - A. If genotype 1, the prescriber has provided the patient's subtype
AND
 - B. If the subtype 1a, the prescriber has tested the patient for NS5A polymorphisms
AND
3. ONE of the following:
 - A. The patient is treatment naïve
OR
 - B. The patient was previously treated (i.e. treatment experienced) with ONLY peg-interferon and ribavirin with or without an HCV protease inhibitor
AND
4. ONE of the following:
 - A. The patient's age is within FDA labeling for the requested indication for the requested agent
OR
 - B. The prescriber has provided information supporting the use of the requested agent for the patient's age
AND
5. The prescriber has screened the patient for current or prior hepatitis B viral (HBV) infection
AND
6. If the HBV screening was positive for current or prior HBV infection, the prescriber will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent
AND
7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist, or infectious disease) or has consulted with a specialist in the area of the patient's diagnosis
AND
8. If the client has preferred agent(s) and/or regimen ONE of the following
 - A. The patient is currently being treated with the non-preferred agent and the patient is currently stable on the non-preferred agent [chart notes are required]
OR
 - B. The patient has an intolerance or hypersensitivity to ALL preferred agent(s) for the patient's specific factors (e.g., age and/or weight, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment) [chart notes are required]
OR
 - C. The patient has an FDA labeled contraindication to ALL preferred agent(s) for the patient's specific factors (e.g., age and/or weight, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment) [chart notes are required]
OR
 - D. The preferred agent(s) for the patient's specific factors (e.g., age and/or weight, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment) is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; **OR** cause a significant barrier to the patient's adherence of care; **OR** worsen a comorbid condition; **OR** decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; **OR** cause an adverse reaction or cause physical or mental harm [chart notes are required]
OR

- E. The preferred agent(s) for the patient's specific factors (e.g., age and/or weight, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment) is not in the best interest of the patient based on medical necessity [chart notes are required]

OR

- F. The prescriber has provided information supporting the use of the non-preferred agent over the preferred agent(s) (e.g., patient is currently taking the requested agent)

AND

9. The patient does NOT have any FDA labeled contraindications to the requested agent

AND

10. The patient meets all requirements and will use the requested agent in a treatment regimen noted in Table 10

AND

11. The requested length of therapy does NOT exceed the length of therapy noted in Table 10 for the patient's treatment regimen

AND

12. The requested quantity (dose) does NOT exceed the program quantity limit

Length of approval:

For BCBSIL members: approve for 6 months

For all other plans: Up to the duration of treatment as determined in Table 10

Table 10: Zepatier Treatment Recommendations based on FDA labeling

Patient Population [£]	Treatment	Duration
Genotype 1a: Treatment-naïve or PegIFN/RBV-experienced <u>without</u> baseline NS5A polymorphisms [†]	Zepatier	12 weeks
Genotype 1a: Treatment-naïve or PegIFN/RBV-experienced <u>with</u> baseline NS5A polymorphisms [†]	Zepatier + ribavirin	16 weeks
Genotype 1b: Treatment-naïve or PegIFN/RBV-experienced	Zepatier	12 weeks
Genotype 1a or 1b: PegIFN/RBV/protease inhibitor-experienced	Zepatier + ribavirin	12 weeks
Genotype 4: Treatment-naïve	Zepatier	12 weeks
Genotype 4: PegIFN/RBV-experienced	Zepatier + ribavirin	16 weeks

[†]Polymorphisms at amino acid positions 28, 30, 31, or 93

[£] HCV/HIV co-infection and/or cirrhosis: follow dosage recommendations in the table above

New to Market Hepatitis C Agents Evaluation

New to market Hepatitis C agents will be approved when ALL of the following are met:

1. The patient has an FDA approved diagnosis for the requested agent

AND

2. The requested agent is FDA approved for treatment of the patient's genotype

AND

3. ONE of the following:

- A. The patient's age is within FDA labeling for the requested indication for the requested agent

OR

- B. The prescriber has provided information supporting the use of the requested agent for the patient's age

AND

4. If FDA labeling for the requested agent requires patients are tested for hepatitis B viral (HBV) infection prior to starting treatment with the requested agent, BOTH of the following:

- A. The prescriber has screened the patient for current or prior HBV

AND

- B. If the HBV screening was positive for current or prior HBV, the prescriber will monitor the patient for HBV flare-up or reactivation during and after treatment with the requested agent

AND

5. The patient does NOT have any FDA labeled contraindications to the requested agent

AND

6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist, or infectious disease) or has consulted with a specialist in the area of the patient's diagnosis

AND

7. ONE of the following:

- A. The requested agent is a preferred agent

OR

- B. The patient is currently being treated with the non-preferred agent and the patient is currently stable on the non-preferred agent [chart notes are required]

OR

- C. The patient has an intolerance or hypersensitivity to ALL preferred agent(s) for the patient's specific factors (e.g., age and/or weight, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment) [chart notes are required]

OR

- D. The patient has an FDA labeled contraindication to ALL preferred agent(s) for the patient's specific factors (e.g., age and/or weight, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment) [chart notes are required]

OR

- E. The preferred agent(s) for the patient's specific factors (e.g., age and/or weight, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment) is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; **OR** cause a significant barrier to the patient's adherence of care; **OR** worsen a comorbid condition; **OR** decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; **OR** cause an adverse reaction or cause physical or mental harm [chart notes are required]

OR

- F. The preferred agent(s) for the patient's specific factors (e.g., age and/or weight, genotype, cirrhosis status, treatment naïve vs treatment experienced, previous treatment) is not in the best interest of the patient based on medical necessity [chart notes are required]

OR

- G. The prescriber has provided information supporting the use of the non-preferred agent over the preferred agent(s) (e.g., patient is currently taking the requested agent)

AND

8. The patient meets all requirements and will use the requested agent in a treatment regimen noted in Table 11

AND

9. The requested length of therapy does NOT exceed the length of therapy noted in Table 11 for the patient's treatment regimen

AND

10. ONE of the following:

- A. The requested quantity (dose) does NOT exceed the program quantity limit

OR

- B. BOTH of the following:

- i. The requested quantity (dose) is greater than the program quantity limit

AND

- ii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

Length of approval:

For BCBSIL members: approve for 6 months

For all other plans: Up to the duration of treatment as determined in Table 11

Table 11: Treatment Recommendations based on FDA labeling

Agent(s)	FDA approved indication(s)	Genotype	Treatment Regimen	FDA labeled dose	Treatment Duration