

Generic Name: Sofosbuvir

Therapeutic Class or Brand Name: Sovaldi®

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 1235308000

Preferred: N/A.

Non-preferred: N/A.

Date of Origin: 2/11/2014

Date Last Reviewed / Revised: 2/12/2020

PRIOR AUTHORIZATION CRITERIA

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

- I. Documented diagnosis of one of the following conditions A or B AND must meet criteria listed under applicable diagnosis:
 - A. Adult patients at least 18 years of age with Chronic Hepatitis C (CHC) Infection AND documentation that patient meets ONE of the following criteria 1 or 2:
 1. Patient has genotypes 1 or 4 infection without cirrhosis or with compensated cirrhosis AND meets both criteria a) and b) below:
 - a) Patient has a documented contraindication or intolerance to Mavyret™, Zepatier™, and Epclusa®.
 - b) Patient will also receive pegylated interferon and ribavirin in combination with Sovaldi®.
 2. Patient has genotypes 2 or 3 infection without cirrhosis or with compensated cirrhosis and meets both criteria a) and b) below:
 - a) Patient has documented contraindication or intolerance to Mavyret™ and Epclusa®.
 - b) Patient will receive ribavirin in combination with Sovaldi®.
 - B. Pediatric patients 3 to 11 years of age with Chronic Hepatitis C (CHC) Infection (confirmed genotype 2 or 3) AND documentation that patient meets all of the following criteria 1 and 2:
 1. Patient does not have cirrhosis or has compensated cirrhosis (Child-Pugh A)
 2. Sovaldi® is prescribed in combination with ribavirin.
- II. Documentation of patient's Hepatitis C treatment history and baseline viral load.
- III. Documentation that patient's hepatitis C drug therapy is prescribed as outlined in Tables 1 or 2 under Authorization in the Approval Length section.
- IV. Prescriber is a Gastroenterologist, Infectious Disease Specialist, or Hepatologist.

Exclusion Criteria

- As retreatment when there has been relapse after, or no response to, a prior treatment course with Epclusa® (sofosbuvir/velpatasvir), Harvoni® (ledipasvir/sofosbuvir), Mavyret™ (glecaprevir/pibrentasvir), Vosevi® (sofosbuvir/velpatasvir/voxilaprevir), or Zepatier™ (elbasvir/grazoprevir).
- Coadministration of Sovaldi® with any of the drugs listed in the table below:

Drug Class	Drugs within class
Antiarrhythmics	Amiodarone when combined with another direct acting antiviral [i.e. daclatasvir, Olysio® (simeprevir)]
Anticonvulsants	Carbamazepine, oxcarbazepine, phenobarbital, phenytoin
Antimycobacterials	Rifabutin, rifampin, rifapentine
Herbal Supplements	St. John's wort (<i>Hypericum perforatum</i>)
HIV Protease Inhibitors	Tipranavir/ritonavir
Other polymerase inhibitors used to treat chronic hepatitis C virus infection	Epclusa® (sofosbuvir/velpatasvir), Harvoni® (ledipasvir/sofosbuvir), Mavyret™ (glecaprevir/pibrentasvir), Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)

OTHER CRITERIA

- N/A.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Patient weight > or = 35 kg: 28 tablets or 56 packets of pellets per 28 days.
- Patient weight < 35 kg: 28 tablets or packets of pellets per 28 days.

APPROVAL LENGTH

- Authorization:** See tables directly below. Table 1 contains information for genotypes 1 through 6, and table 2 contains information for patients with hepatocellular carcinoma.

Table 1. Authorization information for Genotypes 1 through 6.

Drug Therapy	Cirrhosis	G1a		G1b		G2		G3		G4		G5		G6	
		TN	TE	TN	TE	TN	TE	TN	TE	TN	TE	TN	TE	TN	TE
Sovaldi® + pegIFN + RBV	No	12w		12w						12w					
	Comp	12w		12w						12w					
Sovaldi® + RBV	No					12w	12w ¹	24w	24w ¹						
	Comp					12w	12w ¹	24w	24w ¹						

Table 1. Authorization information for Genotypes 1 through 6.

Drug Therapy	Cirrhosis	G1a		G1b		G2		G3		G4		G5		G6	
		TN	TE	TN	TE	TN	TE	TN	TE	TN	TE	TN	TE	TN	TE

TN = treatment naïve; TE = treatment experienced; Comp = compensated; Decomp = decompensated;

RBV = ribavirin; pegIFN = peginterferon; w = weeks

ⁿOnly for patients who have tested negative for the Q80K variant.

[~]RAS testing for Y93H is recommended. If present, ribavirin should be added to the regimen.

[^]For patients who develop HCV infection post-liver transplantation.

¹For patients who have failed pegIFN/RBV.

Table 2. Authorization Information for Patients with Hepatocellular Carcinoma.

Drug Therapy	Patient Characteristics	Authorization Duration
Sovaldi® + RBV	Hepatocellular Carcinoma Awaiting Liver Transplantation	Up to 48 weeks (or until liver transplantation, whichever occurs first)

RBV = ribavirin

- **Re-Authorization:** N/A.

APPENDIX

N/A.

REFERENCES

1. <http://hcvguidelines.org/full-report-view> .
2. Medi-Span®.
3. http://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/sovaldi/sovaldi_pi.pdf .
4. <http://www.fda.gov/Drugs/DrugSafety/ucm439484.htm> .
5. https://pdf.hres.ca/dpd_pm/00039964.PDF .

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
2/12/2020	1. Deleted items under References: http://www.bcbsnc.com/assets/services/public/pdfs/formulary/sovaldi_um_2015_criteria.pdf .

<http://blue.regence.com/trgmedpol/drugs/dru332b.pdf> .
<http://www.olygio.com/shared/product/olygio/prescribing-information.pdf> .
http://packageinserts.bms.com/pi/pi_daklinza.pdf .

2. **Changed item 1-A under Prior Authorization Criteria**

From:

I. Documented diagnosis of one of the following conditions A through C AND must meet criteria listed under applicable diagnosis:

A. Chronic Hepatitis C (CHC) Infection (confirmed genotypes 1, 2, 3, 4, 5 or 6) AND documentation that patient meets ONE of the following criteria 1 through 4:

1. Patient has genotypes 1 or 4 AND meets ONE of criteria a through c:
 - a) Patient has a documented contraindication to Mavyret™, Zepatier™, and Epclusa®.
 - b) Patient has decompensated cirrhosis (Child-Pugh B or C) AND meets BOTH of criteria 1) and 2):
 - 1) Patient has a documented contraindication to Epclusa® and Harvoni®.
 - 2) Patient meets ONE of criteria i or ii
 - (i) Daklinza® + Sovaldi® are prescribed in combination with ribavirin.
 - (ii) Patient has a documented intolerance or contraindication to ribavirin.
 - c) Patient is post-liver transplant and patient has a documented contraindication to Mavyret™ and Harvoni®.
2. Patient has genotype 2 and meets ONE of criteria a through c:
 - a) Patient has a documented contraindication to Mavyret™ and Epclusa®.
 - b) Patient has decompensated cirrhosis (Child-Pugh B or C) AND meets BOTH of criteria 1) and 2):
 - 1) Patient has a documented contraindication to Epclusa®.
 - 2) Patient meets ONE of criteria i or ii:
 - (i) Daklinza® + Sovaldi® are prescribed in combination with ribavirin.
 - (ii) Patient has a documented intolerance or contraindication to ribavirin.
 - c) Patient is post-liver transplant and meets ONE of criteria 1) through 3):
 - 1) Patient does not have cirrhosis and has a documented contraindication to Mavyret™.
 - 2) Patient has compensated cirrhosis, and has a documented contraindication to Mavyret™ and Epclusa®.
 - 3) Patient has decompensated cirrhosis, and has a documented contraindication to Epclusa®.
3. Patient has genotype 3 AND meets ONE of criteria a through c:
 - a) Patient has a documented contraindication to Mavyret™, Zepatier™, and Epclusa®.
 - b) Patient has decompensated cirrhosis (Child-Pugh B or C) and meets BOTH of criteria 1) and 2):
 - 1) Patient has a documented contraindication to Epclusa®.

- 2) Patient meets ONE of criteria i or ii:
 - (i) Daklinza® + Sovaldi® are prescribed in combination with ribavirin.
 - (ii) Patient has a documented intolerance or contraindication to ribavirin.
- c) Patient is post-liver transplant and meets criterion aa:
 - 1) Patient has a documented contraindication to Mavyret™ and Epclusa®.
- 2. Patient has genotypes 5 or 6 and has a documented contraindication to Mavyret™ and Harvoni®.

To:

- 1. Documented diagnosis of one of the following conditions A or B AND must meet criteria listed under applicable diagnosis:
 - A. Adult patients at least 18 years of age with Chronic Hepatitis C (CHC) Infection AND documentation that patient meets ONE of the following criteria 1 or 2:
 - 1. Patient has genotypes 1 or 4 infection without cirrhosis or with compensated cirrhosis AND meets both criteria a) and b) below:
 - a) Patient has a documented contraindication or intolerance to Mavyret™, Zepatier™, and Epclusa®.
 - b) Patient will also receive pegylated interferon and ribavirin in combination with Sovaldi®.
 - 2. Patient has genotypes 2 or 3 infection without cirrhosis or with compensated cirrhosis and meets both criteria a) and b) below:
 - a) Patient has documented contraindication or intolerance to Mavyret™, Zepatier™, and Epclusa®.
 - b) Patient will receive ribavirin in combination with Sovaldi®.
 - B. Pediatric patients 3 to 11 years of age with Chronic Hepatitis C (CHC) Infection (confirmed genotype 2 or 3) AND documentation that patient meets all of the following criteria 1 and 2:
 - 1. Patient does not have cirrhosis or has compensated cirrhosis (Child-Pugh A)
 - 2. Sovaldi® is prescribed in combination with ribavirin.
- 3. Deleted item I-B "Patient is at least 18 years of age with Hepatocellular Carcinoma and hepatitis awaiting liver transplantation" **under Prior Authorization Criteria.**
- 4. **Added** item I-B **under Prior Authorization Criteria** to address new label indication for pediatric patients:
 - B. Pediatric patient 3 to 11 years of age with Chronic Hepatitis C (CHC) Infection (confirmed genotype 2 or 3) AND documentation that patient meets all of the following criteria 1 and 2:
 - 1. Patient does not have cirrhosis or has compensated cirrhosis (Child-Pugh A)
 - 2. Sovaldi® is prescribed in combination with ribavirin.
- 5. **Deleted** item IV "Minimum age requirement: 12 years old." **under Prior Authorization Criteria.**

6. **Deleted** all references to Daklinza® (daclatasvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir) **under Exclusion Criteria** (products discontinued).
7. **Deleted** footnote #1 in Table 1 **under Approval Length** (deletion location noted by red circles):

Drug Therapy	Cirrhosis	G1a		G1b		G2		G3	
		TN	TE	TN	TE	TN	TE	TN	TE
Zepatier™ + Sovaldi®	No							12w	
	Comp							12w	12w ¹
Sovaldi® + RBV	No					12w	12w ¹	24w	24w ¹
	Comp					12w	12w ¹	24w	24w ¹

8. **Changed** Table 1 **under Approval Length** (see screen shot in item7 above) from Zepatier + Sovaldi regiment to Sovaldi + pegylated interferon + ribavirin regiment per package insert section 2.2:

Drug Therapy	Cirrhosis	G1a		G1b		G2		G3		G4		G5
		TN	TE	TN	TE	TN	TE	TN	TE	TN	TE	TN
Sovaldi® + pegIFN + RBV	No	12w		12w							12w	
	Comp	12w		12w							12w	
Sovaldi® + RBV	No					12w	12w ¹	24w	24w ¹			
	Comp					12w	12w ¹	24w	24w ¹			

9. **Changed under Quantity/Days Supply Restrictions** per Table 3 of Sovaldi® package insert:

From:

- 28 tablets per 28 days

To:

- Patient weight > or = 35 kg: 28 tablets or 56 packets of pellets per 28 days.
- Patient weight < 35 kg: 28 tablets or packets of pellets per 28 days.

12/6/2018

1. **Deleted** the following under the Prior Authorization Criteria section I:

	<ol style="list-style-type: none"> 1. Documentation that patient meets ONE of the following criteria a, b, or c: <ol style="list-style-type: none"> A. Has a Metavir score of F3 (advanced fibrosis) or F4 (compensated cirrhosis). B. Is post-liver transplant. C. Has clinically severe extrahepatic manifestations of hepatitis C infection as evidenced by one of the following i or ii: <ol style="list-style-type: none"> 1. Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (i.e. vasculitis). 2. Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis.
<p>11/2/2017</p>	<ol style="list-style-type: none"> 1. Changed "I. A. Chronic Hepatitis C (CHC) Infection with confirmed genotypes 1, 2, 3, or 4..." to "I. A. Chronic Hepatitis C (CHC) Infection with confirmed genotypes 1, 2, 3, 4, 5, or 6" under Prior Authorization Criteria. 2. Changed "I. A. 2. a. i. Patient has a documented contraindication to Zepatier™ and Epclusa®" to "I. A. 2. a. i. Patient has a documented contraindication to Mavyret™, Zepatier™, and Epclusa®" under Prior Authorization Criteria. 3. Changed "I. A. 2. a. ii. Patient has decompensated cirrhosis (Child-Pugh B) AND meets BOTH of criteria aa and ab: aa. Patient has a documented contraindication to Epclusa® and Harvoni®; ab. Sovaldi® is prescribed in combination with Daklinza® and ONE of criteria 1) or 2) is met: 1) Daklinza® + Sovaldi® are prescribed in combination with ribavirin; 2) Patient has a documented intolerance or contraindication to ribavirin" to "I. A. 2. a. ii. Patient has decompensated cirrhosis (Child-Pugh B or C) AND meets BOTH of criteria aa and ab: aa. Patient has a documented contraindication to Epclusa® and Harvoni®; ab. Patient meets ONE of criteria 1) or 2): 1) Daklinza® + Sovaldi® are prescribed in combination with ribavirin; 2) Patient has a documented intolerance or contraindication to ribavirin" under Prior Authorization Criteria. 4. Changed "I. A. 2. a. iii. Patient is post-liver transplant and meets BOTH of criteria aa and ab: aa. Patient has a documented contraindication to Harvoni®; ab. Patient meets ONE of criteria 1) or 2): 1) Sovaldi® is prescribed in combination with Olysio® for genotype 1; 2) Sovaldi® is prescribed in combination with Daklinza® and ONE of criteria ba or bb is met: ba. Daklinza® + Sovaldi® are prescribed in combination with ribavirin; bb. Patient has a documented intolerance or contraindication to ribavirin" to "I. A. 2. a. iii. Patient is post-liver transplant and criterion aa is met: aa. Patient has a documented contraindication to Mavyret™ and Harvoni®" under Prior Authorization Criteria. 5. Changed "I. A. 2. b. Patient has genotype 2 and meets ONE of criteria i or ii: i. Patient has a documented contraindication to Epclusa®; ii. Patient is post-liver transplant and meets ONE of criteria aa or ab: aa. Sovaldi® is prescribed in combination with Daklinza® and ONE of criteria 1) or 2) is met: 1) Daklinza® + Sovaldi® are prescribed in combination with ribavirin; 2) Patient has a documented

intolerance or contraindication to ribavirin; ab. Patient has a documented contraindication to Daklinza®" to "I. A. 2. b. Patient has genotype 2 and meets ONE of criteria i through iii: i. Patient has a documented contraindication to Mavyret™ and Epclusa®; ii. Patient has decompensated cirrhosis (Child-Pugh B or C) AND meets BOTH of criteria aa and ab: aa. Patient has a documented contraindication to Epclusa®; ab. Patient meets ONE of criteria 1) or 2): 1) Daklinza® + Sovaldi® are prescribed in combination with ribavirin; 2) Patient has a documented intolerance or contraindication to ribavirin; iii. Patient is post-liver transplant and meets ONE of criteria aa through ac: aa. Patient does not have cirrhosis and criterion 1) is met: 1) Patient has a documented contraindication to Mavyret™; ab. Patient has compensated cirrhosis, and criterion 1) is met: 1) Patient has a documented contraindication to Mavyret™ and Epclusa®; ac. Patient has decompensated cirrhosis, and criterion 1) is met: 1) Patient has a documented contraindication to Epclusa®" **under Prior Authorization Criteria.**

6. **Changed** "I. A. 2. c. Patient has genotype 3 AND meets ONE of criteria i through iii: i. Patient has a documented contraindication to Epclusa® and Zepatier™; ii. Patient has decompensated cirrhosis (Child-Pugh B) and criterion aa is met: aa. Patient has a documented contraindication to Epclusa®; iii. Patient is post-liver transplant and meets criterion aa: aa. Sovaldi® is prescribed in combination with Daklinza® and ONE of criteria 1) or 2) is met: 1) Daklinza® + Sovaldi® are prescribed in combination with ribavirin; ab. Patient has a documented intolerance or contraindication to ribavirin" to "I. A. 2. c. Patient has genotype 3 AND meets ONE of criteria i through iii: i. Patient has a documented contraindication to Mavyret™, Zepatier™, and Epclusa®; ii. Patient has decompensated cirrhosis (Child-Pugh B or C) and meets BOTH of criteria aa and ab: aa. Patient has a documented contraindication to Epclusa®; ab. Patient meets ONE of criteria 1) or 2): 1) Daklinza® + Sovaldi® are prescribed in combination with ribavirin; 2) Patient has a documented intolerance or contraindication to ribavirin; iii. Patient is post-liver transplant and meets criterion aa: aa. Patient has a documented contraindication to Mavyret™ and Epclusa®" **under Prior Authorization Criteria.**
7. **Added** "I. A. 2. d. Patient has genotypes 5 or 6 and criterion i is met: i. Patient has a documented contraindication to Mavyret™ and Harvoni®" **under Prior Authorization Criteria.**
8. **Updated** "IV. Minimum age requirement: 18 years old" to "Minimum age requirement: 12 years old" **under Prior Authorization Criteria.**
9. **Added** "Mavyret™ (glecaprevir/pibrentasvir)" and "Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)" to list of drugs following the statement "As retreatment when there has been relapse after, or no response to, a prior treatment course with..." **under Exclusion Criteria.**
10. **Removed** "Child-Pugh C" **from Exclusion Criteria.**
11. **Added** "Mavyret™ (glecaprevir/pibrentasvir)" and "Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)" **under Exclusion Criteria** to table under "Coadministration of Sovaldi® with...", line entitled "Other polymerase inhibitors used to treat chronic hepatitis C virus infection".
12. **Changed** "See tables directly below. Table 1 contains information for genotypes 1 through 4..." to "See tables directly below. Table 1 contains information for genotypes 1 through 6..." **following Authorization under Approval Length.**
13. **Changed table 1 below Authorization under Approval Length from (changes made highlighted in yellow):**

Table 1. Authorization information for Genotypes 1 through 4.

Drug Therapy	Cirrhosis	Authorization Duration									
		G1a		G1b		G2		G3		G4	
		TN	TE	TN	TE	TN	TE	TN	TE	TN	TE
Zepatier™ + Sovaldi®	No							12w			
	Comp							12w			
Sovaldi® + RBV	No & Post Transplant [^]					24w [^]	24w [^]				
	Comp & Post Transplant [^]					24w [^]	24w [^]				
	Decomp & Post Transplant [^]					24w [^]	24w [^]				
Olysio® + Sovaldi®	No	12w	12w ¹	12w	12w ¹						
	No & Post Transplant [^]	12w [^]		12w [^]							
	Comp	24w ⁿ	24w ⁿ¹	24w	24w ¹						
	Comp & Post Transplant [^]	12w [^]		12w [^]							
Daklinza® + Sovaldi®	No	12w	12w ⁵	12w	12w ⁵	12w	12w ¹ , 24w ²	12w	12w ¹		
	No & Post Transplant [^]	24w [^]		24w [^]		24w [^]	24w [^]	24w [^]	24w [^]	24w [^]	
	Comp	24w	24w ⁵	24w	24w ⁵	16-24w	16-24w ¹ , 24w ²	24w			
	Comp & Post Transplant [^]	24w [^]		24w [^]		24w [^]	24w [^]	24w [^]	24w [^]	24w [^]	
	Decomp	24w	24w	24w	24w					24w	24w
Daklinza® + Sovaldi® + RBV	No								24w ²		
	No & Post Transplant [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]
	Comp								24w ^{1,2}		
	Comp & Post Transplant [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]
	Decomp	12w	12w	12w	12w	12w	12w	12w	12w	12w	12w

TN = treatment naïve; TE = treatment experienced; Comp = compensated; Decomp = decompensated;

RBV = ribavirin; pegIFN = peginterferon; w = weeks

ⁿOnly for patients who have tested negative for the Q80K variant.

[^]For patients who develop HCV infection post-liver transplantation.

¹For patients who have failed pegIFN/RBV.

²For patients who have failed sofosbuvir + RBV.

⁵For patients who have failed pegIFN/RBV +/- a NS3 protease inhibitor.

to:

Table 1. Authorization information for Genotypes 1 through 6.

Drug Therapy	Cirrhosis	G1a		G1b		G2		G3		G4		G5		G6
		TN	TE	TN	TE	TN	TE	TN	TE	TN	TE	TN	TE	TN
Zepatier™ + Sovaldi®	No							12w						
	Comp							12w	12w ¹					
Sovaldi® + RBV	No					12w	12w ¹	24w ¹	24w ¹					
	Comp					12w	12w ¹	24w ¹	24w ¹					
Olysio® + Sovaldi®	No	12w	12w ¹	12w	12w ¹									
	No & Post Transplant [^]	12w [^]	12w [^]	12w [^]	12w [^]					12w [^]	12w [^]			
	Comp	24w ⁿ	24w ⁿ¹	24w	24w ¹									
	Comp & Post Transplant [^]	12w [^]	12w [^]	12w [^]	12w [^]					12w [^]	12w [^]			
Daklinza® + Sovaldi®	No	12w	12w ¹	12w	12w ¹	12w	12w ¹	12w	12w ¹					
	Comp	12w		12w		16-24w	16-24w ¹	24w [~]						
	Decomp	24w		24w		24w		24w		24w				
Daklinza® + Sovaldi® + RBV	No													
	No & Post Transplant [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]
	Comp							12w, 24w [~]						
	Comp & Post Transplant [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]
	Decomp	12w		12w		12w		12w		12w				
	Decomp & Post Transplant [^]					12w [^]	12w [^]	12w [^]	12w [^]					

TN = treatment naïve; TE = treatment experienced; Comp = compensated; Decomp = decompensated; RBV = ribavirin; pegIFN = peginterferon; w = weeks

	<p>ⁿOnly for patients who have tested negative for the Q80K variant. ⁿRAS testing for Y93H is recommended. If present, ribavirin should be added to the regimen. [^]For patients who develop HCV infection post-liver transplantation. ¹For patients who have failed pegIFN/RBV.</p> <p>1. Updated "http://www.merck.ca/assets/en/pdf/products/ZEPATIER-PM_E.pdf" to "https://pdf.hres.ca/dpd_pm/00039964.PDF" under References.</p>
<p>8/12/2016</p>	<ol style="list-style-type: none"> 1. Changed "Daklinza™" to "Daklinza®" throughout policy. 2. Changed "I. A. Chronic Hepatitis C (CHC) Infection with confirmed genotypes 1, 2, 3, 4, 5, or 6 AND..." to "I. A. Chronic Hepatitis C (CHC) Infection with confirmed genotypes 1, 2, 3, or 4 AND..." under Prior Authorization Criteria. 3. Changed "I. A. 2. a. i. Patient has a documented contraindication to Zepatier™" to "I. A. 2. a. i. Patient has a documented contraindication to Zepatier™ and Epclusa®" under Prior Authorization Criteria. 4. Changed "I. A. 2. a. ii. Patient has decompensated cirrhosis (Child-Pugh B or C)" to "I. A. 2. a. ii. Patient has decompensated cirrhosis (Child-Pugh B) AND meets BOTH of criteria aa and ab: aa. Patient has a documented contraindication to Epclusa® and Harvoni®; ab. Sovaldi® is prescribed in combination with Daklinza® and ONE of criteria 1) or 2) is met: 1) Daklinza® + Sovaldi® are prescribed in combination with ribavirin; 2) Patient has a documented intolerance or contraindication to ribavirin" under Prior Authorization Criteria. 5. Changed "I. A. 2. a. iii. Patient is post-liver transplant" to "I. A. 2. a. iii. Patient is post-liver transplant and meets BOTH of criteria aa and ab: aa. Patient has a documented contraindication to Harvoni®; ab. Patient meets ONE of criteria 1) or 2): 1) Sovaldi® is prescribed in combination with Olysio® for genotype 1; 2) Sovaldi® is prescribed in combination with Daklinza® and ONE of criteria ba or bb is met: ba. Daklinza® + Sovaldi® are prescribed in combination with ribavirin; bb. Patient has a documented intolerance or contraindication to ribavirin" under Prior Authorization Criteria. 6. Changed "I. A. 2. b. Patient has genotypes 2, 5, or 6" to "I. A. 2. b. b. Patient has genotype 2 and meets ONE of criteria i or ii: i. Patient has a documented contraindication to Epclusa®; ii. Patient is post-liver transplant and meets ONE of criteria aa or ab: aa. Sovaldi® is prescribed in combination with Daklinza® and ONE of criteria 1) or 2) is met: 1) Daklinza® + Sovaldi® are prescribed in combination with ribavirin; 2) Patient has a documented intolerance or contraindication to ribavirin; ab. Patient has a documented contraindication to Daklinza®" under Prior Authorization Criteria. 7. Changed "I. A. 2. c. Patient has genotype 3 AND meets ONE of criteria i through iv: i. Patient has a documented contraindication to Zepatier™; ii. Patient has decompensated cirrhosis (Child-Pugh B or C); iii. Patient is post-liver transplant; iv. Patient has failed prior treatment with peginterferon + ribavirin OR Sovaldi® + ribavirin" to "I. A. 2. c. Patient has genotype 3 AND meets ONE of criteria i through iii: i. Patient has a documented contraindication to Epclusa® and Zepatier™; ii. Patient has decompensated cirrhosis (Child-Pugh B) and criterion aa is met: aa. Patient has a documented contraindication to Epclusa®; iii. Patient is post-liver transplant and meets criterion aa: aa. Sovaldi® is prescribed in combination with Daklinza® and ONE of criteria 1) or 2) is met: 1) Daklinza® + Sovaldi® are prescribed in combination with ribavirin; Patient has a documented intolerance or contraindication to ribavirin" under Prior Authorization Criteria.

8. **Changed** "III. ...as outlined in Tables 1, 2, or 3 under Authorization in the Approval Length section" **to** "III. ...as outlined in Tables 1 or 2 under Authorization in the Approval Length section" **under Prior Authorization Criteria**.
9. **Added** "Epclusa® (sofosbuvir/velpatasvir)" **under Exclusion Criteria** to: 1) List of drugs following the statement "As retreatment when there has been relapse after, or no response to, a prior treatment course with..."; 2) table under "Coadministration of Sovaldi® with...", line entitled "Other polymerase inhibitors used to treat chronic hepatitis C virus infection".
10. **Changed** "Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir/dasabuvir)" **to** "Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir)" in list of drugs following the statement "As retreatment when there has been relapse after, or no response to, a prior treatment course with..." **under Exclusion Criteria**.
11. **Added** "Child-Pugh C" **under Exclusion Criteria**.
12. **Changed** "Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir/dasabuvir)" **to** "Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir)" **under Exclusion Criteria** to table under "Coadministration of Sovaldi® with...", line entitled "Other polymerase inhibitors used to treat chronic hepatitis C virus infection".
13. **Changed** "See tables directly below. Table 1 contains information for genotypes 1 through 3, table 2 contains information for genotypes 4 through 6, and table 3 contains information for hepatocellular carcinoma" **to** "See tables directly below. Table 1 contains information for genotypes 1 through 4, and table 2 contains information for hepatocellular carcinoma" **following Authorization under Approval Length. Changed tables from (changes made highlighted in yellow):**

Table 1. Authorization information for Genotypes 1 through 3.

Drug Therapy	Cirrhosis	Authorization Duration							
		G1a		G1b		G2		G3	
		TN	TE	TN	TE	TN	TE	TN	TE
Zepatier™ + Sovaldi®	No							12w	
	Comp							12w	
Sovaldi® + RBV	No					12w	12w ¹	24w	
	No & Post Transplant [^]					24w [^]	24w [^]	24w [^]	24w [^]
	Comp					16-24w	16-24w ¹	24w	
	Comp & Post Transplant [^]					24w [^]	24w [^]	24w [^]	24w [^]
	Decomp & Post Transplant [^]					24w [^]	24w [^]		
Sovaldi® + pegIFN/RBV	No						12w ²	12w	12w ¹
	Comp						12w ^{1,2}	12w	12w ¹
Olysio® + Sovaldi®	No	12w	12w ¹	12w	12w ¹				
	No & Post Transplant [^]	12w [^]		12w [^]					
	Comp	24w ⁿ	24w ⁿ¹	24w	24w ¹				

	Comp & Post Transplant [^]	12w [^]		12w [^]					
Daklinza® + Sovaldi®	No	12w	12w ⁵	12w	12w ⁵	12w	12w ¹ , 24w ²	12w	12w ¹
	No & Post Transplant [^]	24w [^]		24w [^]		24w [^]	24w [^]	24w [^]	24w [^]
	Comp	24w	24w ⁵	24w	24w ⁵	16-24w	16-24w ¹ , 24w ²	24w	
	Comp & Post Transplant [^]	24w [^]		24w [^]		24w [^]	24w [^]	24w [^]	24w [^]
	Decomp	24w		24w					
Daklinza® + Sovaldi® + RBV	No								24w ²
	No & Post Transplant [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]
	Comp								24w ^{1,2}
	Comp & Post Transplant [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]
	Decomp	12w		12w		12w		12w	

TN = treatment naïve; TE = treatment experienced; Comp = compensated; Decomp = decompensated;

RBV = ribavirin; pegIFN = peginterferon; w = weeks

ⁿOnly for patients who have tested negative for the Q80K variant.

[^]For patients who develop HCV infection post-liver transplantation.

¹For patients who have failed pegIFN/RBV.

^{1a}For patients who experienced virologic relapse after prior pegIFN/RBV therapy.

^{1b}For patients who experienced on-treatment virologic failure while on prior pegIFN/RBV therapy.

²For patients who have failed sofosbuvir + RBV.

⁵For patients who have failed pegIFN/RBV +/- a NS3 protease inhibitor.

Table 2. Authorization information for Genotypes 4 through 6.

Drug Therapy	Cirrhosis	Authorization Duration					
		G4		G5		G6	
		TN	TE	TN	TE	TN	TE
Sovaldi® + RBV	No		24w				
	No & Post Transplant [^]						
	Comp		24w				
	Comp & Post Transplant [^]						
	Decomp & Post Transplant [^]						
Sovaldi® + pegIFN/RBV	No	12w	12w	12w	12w ¹	12w	12w ¹
	Comp	12w	12w	12w	12w ¹	12w	12w ¹
	No						

Daklinza® + Sovaldi®	No & Post Transplant [^]	24w [^]						
	Comp							
	Comp & Post Transplant [^]	24w [^]						
	Decomp	24w						
Daklinza® + Sovaldi® + RBV	No							
	No & Post Transplant [^]	12w [^]	12w [^]					
	Comp							
	Comp & Post Transplant [^]	12w [^]	12w [^]					
	Decomp	12w						

TN = treatment naive; TE = treatment experienced; Comp = compensated; Decomp = decompensated; RBV = ribavirin; pegIFN = peginterferon; w = weeks

[^]For patients who develop HCV infection post-liver transplantation.

¹For patients who have failed pegIFN/RBV.

Table 3. Authorization Information for Hepatocellular Carcinoma.

Drug Therapy	Patient Characteristics	Authorization Duration
Sovaldi® + RBV	Hepatocellular Carcinoma Awaiting Liver Transplantation	Up to 48 weeks (or until liver transplantation, whichever occurs first)

RBV = ribavirin

to:

Table 1. Authorization information for Genotypes 1 through 4.

Drug Therapy	Cirrhosis	Authorization Duration									
		G1a		G1b		G2		G3		G4	
		TN	TE	TN	TE	TN	TE	TN	TE	TN	TE
Zepatier™ + Sovaldi®	No							12w			
	Comp							12w			
Sovaldi® + RBV	No & Post Transplant [^]					24w [^]	24w [^]				
	Comp & Post Transplant [^]					24w [^]	24w [^]				
	Decomp & Post Transplant [^]					24w [^]	24w [^]				
Olysio® + Sovaldi®	No	12w	12w ¹	12w	12w ¹						
	No & Post Transplant [^]	12w [^]		12w [^]							
	Comp	24w ⁿ	24w ⁿ ₁	24w	24w ¹						
	Comp & Post Transplant [^]	12w [^]		12w [^]							

Daklinza® + Sovaldi®	No	12w	12w ⁵	12w	12w ⁵	12w	12w ¹ , 24w ²	12w	12w ¹		
	No & Post Transplant [^]	24w [^]		24w [^]		24w [^]	24w [^]	24w [^]	24w [^]	24w [^]	
	Comp	24w	24w ⁵	24w	24w ⁵	16- 24w	16- 24w ¹ , 24w ²	24w			
	Comp & Post Transplant [^]	24w [^]		24w [^]		24w [^]	24w [^]	24w [^]	24w [^]	24w [^]	
	Decomp	24w	24w	24w	24w					24w	24w
Daklinza® + Sovaldi® + RBV	No								24w ²		
	No & Post Transplant [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]
	Comp								24w ¹ , 2		
	Comp & Post Transplant [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]
	Decomp	12w	12w	12w	12w	12w	12w	12w	12w	12w	12w

TN = treatment naïve; TE = treatment experienced; Comp = compensated; Decomp = decompensated;

RBV = ribavirin; pegIFN = peginterferon; w = weeks

ⁿOnly for patients who have tested negative for the Q80K variant.

[^]For patients who develop HCV infection post-liver transplantation.

¹For patients who have failed pegIFN/RBV.

²For patients who have failed sofosbuvir + RBV.

⁵For patients who have failed pegIFN/RBV +/- a NS3 protease inhibitor.

Table 2. Authorization Information for Hepatocellular Carcinoma.

Drug Therapy	Patient Characteristics	Authorization Duration
Sovaldi® + RBV	Hepatocellular Carcinoma Awaiting Liver Transplantation	Up to 48 weeks (or until liver transplantation, whichever occurs first)

RBV = ribavirin

- **Added** "http://www.merck.ca/assets/en/pdf/products/ZEPATIER-PM_E.pdf" under **References.**

3/21/2016

1. **Changed** "member" to "patient" throughout policy.
2. **Changed** "A2. Sovaldi® must be used in combination with ONE of the following regimens a through I AND member must meet criteria listed with applicable regimen: a. Daklinza™ for genotype 1 and one of criteria i or ii is met: i. Member is treatment-naïve and criterion aa is met: aa Member has a documented intolerance or contraindication to both Harvoni® AND Viekira Pak™; ii. Member has failed prior treatment with one of the following aa, ab, or ac AND meets criteria listed under applicable failed treatment: aa Peginterferon + ribavirin AND criterion 1) is met: 1) Member has a documented intolerance or contraindication to both Harvoni® AND Viekira Pak™; ab Sovaldi® + Olysio® AND criterion 1) is met: 1) Member has a documented intolerance or contraindication to Harvoni®; ac Protease inhibitor + peginterferon alfa + ribavirin AND criterion 1) is met: 1) Member has a documented

intolerance contraindication to Harvoni®; b. Olysio® for genotype 1 AND both of criteria i and 2 are met: i. Member has a documented intolerance or contraindication to both Harvoni® AND Viekira Pak™; ii. Member meets one of criteria aa or ab: aa Member is treatment-naïve; ab Member has failed prior treatment with peginterferon + ribavirin; c. Ribavirin for genotype 2 AND one of criteria i or ii is met: i. Member is treatment-naïve; ii. Member has failed prior treatment with peginterferon + ribavirin; d. Peginterferon alfa + ribavirin for genotype 2 in members who have failed prior treatment with one of the following i or ii: i. Peginterferon + ribavirin; ii. Sovaldi® + ribavirin; e. Daklinza™ for genotype 2 AND one of criteria i or ii is met: i. Member is treatment-naïve and criterion aa is met: aa Member has a documented intolerance or contraindication to ribavirin; ii. Member has failed prior treatment with Sovaldi + ribavirin AND meets criterion aa below: aa Member has documented intolerance or contraindication to peginterferon; f. Peginterferon alfa + ribavirin for genotype 3 AND one of criteria i or ii is met: i. Member is treatment-naïve; ii. Member has failed prior treatment with one of the following aa or ab: aa Peginterferon + ribavirin; ab Sovaldi® + ribavirin; g. Ribavirin for genotype 3 AND both criteria i and ii are met: i. Member has documented intolerance or contraindication to peginterferon; ii. Member is treatment-naïve; h. Daklinza™ for genotype 3 AND one of criteria i or ii is met: i. Member is treatment-naïve and criterion aa is met: aa Member has documented intolerance or contraindication to peginterferon; ii. Member meets both of criteria aa and ab: aa Member has documented intolerance or contraindication to peginterferon; ab Member has failed prior treatment with one of the following 1) or 2): 1) Peginterferon + ribavirin; 2) Sovaldi® + ribavirin; i. Daklinza™ + ribavirin for genotype 3 AND both criteria i and ii are met: i. Member has documented intolerance or contraindication to peginterferon; ii. Member meets one of the following criteria aa or ab: aa Member has failed treatment with Sovaldi® + ribavirin; ab Member has cirrhosis AND has failed treatment with peginterferon + ribavirin; j. Peginterferon alfa + ribavirin for genotype 4 AND both of criteria i and ii are met: i. Member has a documented intolerance or contraindication to both Harvoni® AND Technivie™; ii. Member is treatment-naïve or has failed prior treatment with peginterferon + ribavirin; k. Ribavirin for genotype 4 AND all of criteria i through iii are met: i. Member has a documented intolerance or contraindication to both Harvoni® AND Technivie™; ii. Member has documented intolerance or contraindication to peginterferon; iii. Member is treatment-naïve or has failed prior treatment with peginterferon + ribavirin; l. Peginterferon alfa + ribavirin for genotypes 5 or 6 AND criteria i is met: i. Member has a documented intolerance or contraindication to Harvoni®; B. Hepatocellular carcinoma and criteria 1 and 2 are met: 1. The member is awaiting liver transplantation; 2. Sovaldi® must be used in combination with ribavirin;...” to “A2. Documentation that patient meets ONE of the following criteria a, b, or c: a. Patient has genotypes 1 or 4 AND meets ONE of criteria i through iii: i. Patient has a documented contraindication to Zepatier™; ii. Patient has decompensated cirrhosis (Child-Pugh B or C); iii. Patient is post-liver transplant; b. Patient has genotypes 2, 5, or 6; c. Patient has genotype 3 AND meets ONE of criteria i through iv: i. Patient has a documented contraindication to Zepatier™; ii. Patient has decompensated cirrhosis (Child-Pugh B or C); iii. Patient is post-liver transplant; iv. Patient has failed prior treatment with peginterferon + ribavirin OR Sovaldi® + ribavirin; B. Hepatocellular carcinoma and criterion 1 is met: The patient is awaiting liver transplantation;...III. Documentation that patient's hepatitis C drug therapy is prescribed as outlined in Tables 1, 2, or 3 under Authorization in the Approval Length section” **under Prior Authorization Criteria.**

3. **Changed** "As retreatment when there has been relapse after, or no response to, a prior treatment course with Daklinza™ (daclatasvir), Harvoni® (ledipasvir/sofosbuvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), or Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir/dasabuvir)" **to** "As retreatment when there has been relapse after, or no response to, a prior treatment course with Daklinza™ (daclatasvir), Harvoni® (ledipasvir/sofosbuvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir/dasabuvir), or Zepatier™ (elbasvir/grazoprevir)" **under Exclusion Criteria**.
4. **Changed section following Authorization under Approval Length from:**
Authorization: See table directly below.

Patient Characteristics		Sovaldi® Authorization Information	
Genotype, Other Features	Hepatitis C Treatment History	Treatment	Authorization Duration
1a or 1b, without cirrhosis	Treatment-naïve/ Treatment-experienced	Sovaldi® + Daklinza™	12 weeks
		Sovaldi® + Olysio®	
1a or 1b, with cirrhosis	Treatment-naïve/ Treatment-experienced	Sovaldi® + Daklinza™	24 weeks
		Sovaldi® + Olysio®	
2, without cirrhosis	Treatment-naïve	Sovaldi® + ribavirin	12 weeks
		Sovaldi® + Daklinza™	
2, with cirrhosis	Treatment-naïve	Sovaldi® + ribavirin	16 weeks
		Sovaldi® + Daklinza™	12 weeks
2	Treatment-experienced	Sovaldi® + ribavirin	16 to 24 weeks
		Sovaldi® + ribavirin + peginterferon	12 weeks
		Sovaldi® + Daklinza™	24 weeks
3, without cirrhosis	Treatment-naïve	Sovaldi® + ribavirin + peginterferon	12 weeks
		Sovaldi® + Daklinza™	
		Sovaldi® + ribavirin	24 weeks
3, without cirrhosis	Treatment-experienced (<i>failed peginterferon + ribavirin</i>)	Sovaldi® + ribavirin + peginterferon	12 weeks
		Sovaldi® + Daklinza™	
3, without cirrhosis	Treatment-experienced (<i>failed Sovaldi® + ribavirin</i>)	Sovaldi® + ribavirin + peginterferon	12 weeks
		Sovaldi® + Daklinza™ + ribavirin	24 weeks
3, with cirrhosis	Treatment-naïve	Sovaldi® + ribavirin + peginterferon	12 weeks
		Sovaldi® + ribavirin	24 weeks
		Sovaldi® + Daklinza™	
3, with cirrhosis	Treatment-experienced	Sovaldi® + ribavirin + peginterferon	12 weeks
		Sovaldi® + Daklinza™ + ribavirin	24 weeks

4	Treatment-naïve/ Treatment-experienced	Sovaldi® + ribavirin + peginterferon	12 weeks
		Sovaldi® + ribavirin	24 weeks
5 or 6	Treatment-naïve/ Treatment-experienced	Sovaldi® + ribavirin + peginterferon	12 weeks
Hepatocellular Carcinoma Awaiting Liver Transplantation		Sovaldi® + ribavirin	Up to 48 weeks (or until liver transplantation, whichever occurs first)

to:

Authorization: See tables directly below. Table 1 contains information for genotypes 1 through 3, table 2 contains information for genotypes 4 through 6, and table 3 contains information for hepatocellular carcinoma.

Table 1. Authorization information for Genotypes 1 through 3.

Drug Therapy	Cirrhosis	Authorization Duration							
		G1a		G1b		G2		G3	
		TN	TE	TN	TE	TN	TE	TN	TE
Zepatier™ + Sovaldi®	No							12w	
	Comp							12w	
Sovaldi® + RBV	No					12w	12w ¹	24w	
	No & Post Transplant [^]					24w [^]	24w [^]	24w [^]	24w [^]
	Comp					16-24w	16-24w ¹	24w	
	Comp & Post Transplant [^]					24w [^]	24w [^]	24w [^]	24w [^]
	Decomp & Post Transplant [^]					24w [^]	24w [^]		
Sovaldi® + pegIFN/RB V	No						12w ²	12w	12w
	Comp						12w ^{1,2}	12w	12w
Olysio® + Sovaldi®	No	12w	12w ¹	12w	12w ¹				
	No & Post Transplant [^]	12w [^]		12w [^]					
	Comp	24w ⁿ	24w ⁿ¹	24w	24w ¹				
	Comp & Post Transplant [^]	12w [^]		12w [^]					
Daklinza™ + Sovaldi®	No	12w	12w ⁵	12w	12w ⁵	12w	12w ¹ , 24w ²	12w	12w
	No & Post Transplant [^]	24w [^]		24w [^]		24w [^]	24w [^]	24w [^]	24w [^]

	Comp	24w	24w ⁵	24w	24w ⁵	16-24w	16-24w ¹ , 24w ²	24w	
	Comp & Post Transplant [^]	24w [^]		24w [^]		24w [^]	24w [^]	24w [^]	24w [^]
	Decomp	24w		24w					
Daklinza™ + Sovaldi® + RBV	No								24w ²
	No & Post Transplant [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]
	Comp								24w ^{1,2}
	Comp & Post Transplant [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]	12w [^]
	Decomp	12w		12w		12w		12w	

TN = treatment naïve; TE = treatment experienced; Comp = compensated; Decomp = decompensated;

RBV = ribavirin; pegIFN = peginterferon; w = weeks

ⁿOnly for patients who have tested negative for the Q80K variant.

[^]For patients who develop HCV infection post-liver transplantation.

¹For patients who have failed pegIFN/RBV.

^{1a}For patients who experienced virologic relapse after prior pegIFN/RBV therapy.

^{1b}For patients who experienced on-treatment virologic failure while on prior pegIFN/RBV therapy.

²For patients who have failed sofosbuvir + RBV.

⁵For patients who have failed pegIFN/RBV +/- a NS3 protease inhibitor.

Table 2. Authorization information for Genotypes 4 through 6.

Drug Therapy	Cirrhosis	Authorization Duration					
		G4		G5		G6	
		TN	TE	TN	TE	TN	TE
Sovaldi® + RBV	No		24w				
	No & Post Transplant [^]						
	Comp		24w				
	Comp & Post Transplant [^]						
	Decomp & Post Transplant [^]						
Sovaldi® + pegIFN/RBV	No	12w	12w	12w	12w ¹	12w	12w ¹
	Comp	12w	12w	12w	12w ¹	12w	12w ¹
Daklinza™ + Sovaldi®	No						
	No & Post Transplant [^]	24w [^]					
	Comp						
	Comp & Post Transplant [^]	24w [^]					
	Decomp	24w					
	No						

Daklinza™ + Sovaldi® + RBV	No & Post Transplant [^]	12w [^]	12w [^]				
	Comp						
	Comp & Post Transplant [^]	12w [^]	12w [^]				
	Decomp	12w					

TN = treatment naïve; TE = treatment experienced; Comp = compensated; Decomp = decompensated; RBV = ribavirin; pegIFN = peginterferon; w = weeks

[^]For patients who develop HCV infection post-liver transplantation.

¹For patients who have failed pegIFN/RBV.

Table 3. Authorization Information for Hepatocellular Carcinoma.

Drug Therapy	Patient Characteristics	Authorization Duration
Sovaldi® + RBV	Hepatocellular Carcinoma Awaiting Liver Transplantation	Up to 48 weeks (or until liver transplantation, whichever occurs first)

RBV = ribavirin

- **Updated** "http://www.hcvguidelines.org/fullreport" to "http://hcvguidelines.org/full-report-view" **under References.**

12/7/2015

1. **Changed** "2. Sovaldi® must be used in combination with ONE of the following regimens a through e: a. Olysio® for genotype 1 AND criterion i must be met: i. Member has a documented contraindication to both Harvoni® AND Viekira Pak™; b. Ribavirin for genotype 2; c. Peginterferon alfa and ribavirin for genotypes 3, 4, or 5; d. Ribavirin for genotypes 3 or 4 AND criterion i is met: i. Member is peginterferon ineligible (i.e. the patient is intolerant to or has a contraindication to peginterferon); e. Peginterferon alfa and ribavirin for genotype 6 and criterion i must be met: i. Member must have a documented contraindication to Harvoni" **to** "2. Sovaldi® must be used in combination with ONE of the following regimens a through I AND member must meet criteria listed with applicable regimen: a. Daklinza™ for genotype 1 and one of criteria i or ii is met: i. Member is treatment-naïve and criterion aa is met: aa. Member has a documented intolerance or contraindication to both Harvoni® AND Viekira Pak™; ii. Member has failed prior treatment with one of the following aa, ab, or ac AND meets criteria listed under applicable failed treatment: aa. Peginterferon + ribavirin AND criterion 1) is met: 1) Member has a documented intolerance or contraindication to both Harvoni® AND Viekira Pak™; ab. Sovaldi® + Olysio® AND criterion 1) is met: 1) Member has a documented intolerance or contraindication to Harvoni®; ac. Protease inhibitor + peginterferon alfa + ribavirin AND criterion 1) is met: 1) Member has a documented intolerance or contraindication to Harvoni®; b. Olysio® for genotype 1 AND both of criteria i and 2 are met: i. Member has a documented intolerance or contraindication to both Harvoni® AND Viekira Pak™; ii. Member meets one of criteria aa or ab: aa. Member is treatment-naïve; Member has failed prior treatment with peginterferon + ribavirin; c. Ribavirin for genotype 2 AND one of criteria i or ii is met: i. Member is treatment-naïve; ii. Member has failed prior treatment with peginterferon + ribavirin; d. Peginterferon alfa + ribavirin for genotype 2 in members who have failed prior treatment with one of the following i or ii: i. Peginterferon + ribavirin; ii. Sovaldi® + ribavirin; e. Daklinza™ for genotype 2 AND one of criteria i or ii is met: i. Member is

treatment-naïve and criterion aa is met: aa. Member has a documented intolerance or contraindication to ribavirin; ii. Member has failed prior treatment with Sovaldi + ribavirin AND meets criterion aa below: aa. Member has documented intolerance or contraindication to peginterferon; f. Peginterferon alfa + ribavirin for genotype 3 AND one of criteria i or ii is met: i. Member is treatment-naïve; ii. Member has failed prior treatment with one of the following aa or ab: aa Peginterferon + ribavirin; ab Sovaldi® + ribavirin; g. Ribavirin for genotype 3 AND both criteria i and ii are met: i. Member has documented intolerance or contraindication to peginterferon; ii. Member is treatment-naïve; h. Daklinza™ for genotype 3 AND one of criteria i or ii is met: i. Member is treatment-naïve and criterion aa is met: aa. Member has documented intolerance or contraindication to peginterferon; ii. Member meets both of criteria aa and ab: aa. Member has documented intolerance or contraindication to peginterferon; ab. Member has failed prior treatment with one of the following 1) or 2): 1) Peginterferon + ribavirin; 2) Sovaldi® + ribavirin; i. Daklinza™ + ribavirin for genotype 3 AND both criteria i and ii are met: i. Member has documented intolerance or contraindication to peginterferon; ii. Member meets one of the following criteria aa or ab: aa. Member has failed treatment with Sovaldi® + ribavirin; ab. Member has cirrhosis AND has failed treatment with peginterferon + ribavirin; i. Peginterferon alfa + ribavirin for genotype 4 AND both of criteria i and ii are met: i. Member has a documented intolerance or contraindication to both Harvoni® AND Technivie™; ii. Member is treatment-naïve or has failed prior treatment with peginterferon + ribavirin; j. Ribavirin for genotype 4 AND all of criteria i through iii are met: i. Member has a documented intolerance or contraindication to both Harvoni® AND Technivie™; ii. Member has documented intolerance or contraindication to peginterferon; iii. Member is treatment-naïve or has failed prior treatment with peginterferon + ribavirin; k. Peginterferon alfa + ribavirin for genotypes 5 or 6 AND criteria i is met: i. Member has a documented intolerance or contraindication to Harvoni®" **under Prior Authorization Criteria.**

2. **Changed** "II. Documentation of member's Hepatitis C treatment history" **to** "II. Documentation of member's Hepatitis C treatment history and baseline viral load" **under Prior Authorization Criteria.**
3. **Changed** "As retreatment when there has been relapse after, or no response to, a prior treatment course with Harvoni® (ledipasvir/sofosbuvir), Incivek® (telaprevir), Olysio® (simeprevir), Sovaldi® (sofosbuvir), Victrelis® (boceprevir), or Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir /dasabuvir)" **to** "As retreatment when there has been relapse after, or no response to, a prior treatment course with Daklinza™ (daclatasvir), Harvoni® (ledipasvir/sofosbuvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), or Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir/dasabuvir)" **under Exclusion Criteria.**

4. **Changed:**

Patient Characteristics		Sovaldi® Authorization Information	
Genotype, Other Features	Hepatitis C Treatment History	Treatment	Authorization Duration
1a, without cirrhosis	Treatment-naïve/ Treatment-experienced	Sovaldi® + Olysio® +/- ribavirin	12 weeks
1a, with cirrhosis	Treatment-naïve/ Treatment-experienced	Sovaldi® + Olysio® +/- ribavirin	24 weeks
1b, without cirrhosis	Treatment-naïve	Sovaldi® + Olysio®	12 weeks
1b, without cirrhosis	Treatment-experienced	Sovaldi® + Olysio® +/- ribavirin	12 weeks

1b, with cirrhosis	Treatment-naïve	Sovaldi® + Olysio®	24 weeks
1b, with cirrhosis	Treatment-experienced	Sovaldi® + Olysio® +/- ribavirin	24 weeks
2	Treatment-naïve	Sovaldi® + ribavirin	12 weeks
2	Treatment-experienced	Sovaldi® + ribavirin	12 weeks to 16 weeks
2	Treatment-experienced	Sovaldi® + peginterferon alfa + ribavirin	12 weeks
3, 4, 5, or 6	Treatment-naïve/ Treatment-experienced	Sovaldi® + peginterferon alfa + ribavirin	12 weeks
3 or 4	Treatment-naïve/ Treatment-experienced, peginterferon ineligible	Sovaldi® + ribavirin	24 weeks
Hepatocellular Carcinoma Awaiting Liver Transplantation		Sovaldi® + ribavirin	Up to 48 weeks (or until liver transplantation, whichever occurs first)

to:

Patient Characteristics		Sovaldi® Authorization Information	
Genotype, Other Features	Hepatitis C Treatment History	Treatment	Authorization Duration
1a or 1b, without cirrhosis	Treatment-naïve/ Treatment-experienced	Sovaldi® + Daklinza™	12 weeks
		Sovaldi® + Olysio®	
1a or 1b, with cirrhosis	Treatment-naïve/ Treatment-experienced	Sovaldi® + Daklinza™	24 weeks
		Sovaldi® + Olysio®	
2, without cirrhosis	Treatment-naïve	Sovaldi® + ribavirin	12 weeks
		Sovaldi® + Daklinza™	
2, with cirrhosis	Treatment-naïve	Sovaldi® + ribavirin	16 weeks
		Sovaldi® + Daklinza™	12 weeks
2	Treatment-experienced	Sovaldi® + ribavirin	16 to 24 weeks
		Sovaldi® + ribavirin + peginterferon	12 weeks
		Sovaldi® + Daklinza™	24 weeks
3, without cirrhosis	Treatment-naïve	Sovaldi® + ribavirin + peginterferon	12 weeks
		Sovaldi® + Daklinza™	

		Sovaldi® + ribavirin	24 weeks
3, without cirrhosis	Treatment-experienced (failed peginterferon + ribavirin)	Sovaldi® + ribavirin + peginterferon	12 weeks
		Sovaldi® + Daklinza™	
3, without cirrhosis	Treatment-experienced (failed Sovaldi® + ribavirin)	Sovaldi® + ribavirin + peginterferon	12 weeks
		Sovaldi® + Daklinza™ + ribavirin	24 weeks
3, with cirrhosis	Treatment-naïve	Sovaldi® + ribavirin + peginterferon	12 weeks
		Sovaldi® + Daklinza™	24 weeks
3, with cirrhosis	Treatment-experienced	Sovaldi® + ribavirin + peginterferon	12 weeks
		Sovaldi® + Daklinza™ + ribavirin	24 weeks
4	Treatment-naïve/ Treatment-experienced	Sovaldi® + ribavirin + peginterferon	12 weeks
		Sovaldi® + ribavirin	24 weeks
5 or 6	Treatment-naïve/ Treatment-experienced	Sovaldi® + ribavirin + peginterferon	12 weeks
Hepatocellular Carcinoma Awaiting Liver Transplantation		Sovaldi® + ribavirin	Up to 48 weeks (or until liver transplant on, whichever occurs first)

on table following Authorization under Approval Length.

- **Added** " http://packageinserts.bms.com/pi/pi_daklinza.pdf" under References.

4/1/2015

- **Changed** "1. Documentation that member meets ONE of the following criteria a, b, or c: a. Has a Metavir score of F3 (advanced fibrosis) or F4 (compensated cirrhosis); b. Is post-liver transplant; c. Has clinically severe extrahepatic manifestations of hepatitis C infection as evidenced by one of the following i or ii: i. Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (i.e. vasculitis); ii. Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis" to "1. Documentation that member meets ONE of the following criteria a through i: a. Has a Metavir score of F2 (fibrosis), F3 (advanced fibrosis), or F4 (compensated cirrhosis); b. Is post-liver transplant; c. Has clinically severe extrahepatic manifestations of hepatitis C infection as evidenced by one of the following i or ii: i. Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (i.e. vasculitis); ii. Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis; d. Is coinfecting with HIV-1; e. Is coinfecting with Hepatitis B virus (HBV); f. Has other coexistent liver disease [i.e. nonalcoholic steatohepatitis (NASH)]; g. Has debilitating fatigue as evidenced by the documentation of significant limitations of instrumental

	<p>activities of daily living (i.e. meal preparation, household chores, etc.); h. Has Type 2 diabetes mellitus (insulin resistant); i. Has porphyria cutanea tarda" under Prior Authorization Criteria.</p>																								
<p>3/25/2015</p>	<p>1. Added "Antiarrhythmics: Amiodarone when combined with another direct acting antiviral [i.e. daclatasvir, Olysio® (simeprevir)]" on table for "Coadministration of Sovaldi® with any of drugs listed in the table below" under Exclusion Criteria. ✓ Added "http://www.fda.gov/Drugs/DrugSafety/ucm439484.htm" under References.</p>																								
<p>2/7/2015</p>	<p>1. Changed "Sovaldi® must be used in combination with ONE of the following regimens a through f: a. Peginterferon alfa and ribavirin for genotype 1 and criterion i must be met: i. Member must have a documented contraindication to ALL of the following: Harvoni®, Viekira Pak™, AND Olysio®; b. Peginterferon alfa and ribavirin for genotypes 3, 4, or 5; c. Peginterferon alfa and ribavirin for genotype 6 and criterion i must be met: i. Member must have a documented contraindication to Harvoni; d. Olysio® for genotype 1 AND criterion i must be met: i. Member has a documented contraindication to both Harvoni® AND Viekira Pak™; e. Ribavirin for genotype 2; f. Ribavirin for genotypes 1, 3, or 4 AND criteria i and ii are met: i. Member is peginterferon ineligible (i.e. the patient is intolerant to or has a contraindication to peginterferon); ii. For genotype 1, member must also have a documented contraindication to ALL of the following: Harvoni®, Viekira Pak™, AND Olysio®" to "Sovaldi® must be used in combination with ONE of the following regimens a through e: a. Olysio® for genotype 1 AND criterion i must be met: i. Member has a documented contraindication to both Harvoni® AND Viekira Pak™; b. Ribavirin for genotype 2; c. Peginterferon alfa and ribavirin for genotypes 3, 4, or 5; d. Ribavirin for genotypes 3 or 4 AND criterion i is met: i. Member is peginterferon ineligible (i.e. the patient is intolerant to or has a contraindication to peginterferon); e. Peginterferon alfa and ribavirin for genotype 6 and criterion i must be met: i. Member must have a documented contraindication to Harvoni" under Prior Authorization Criteria.</p> <p>2. Changed table under Approval Length from:</p> <table border="1" data-bbox="456 1268 1490 1890"> <thead> <tr> <th>Patient Characteristics</th> <th>Treatment</th> <th>Authorization Duration</th> </tr> </thead> <tbody> <tr> <td>Genotype 1a, without cirrhosis</td> <td>Sovaldi® + Olysio® +/- ribavirin</td> <td>12 weeks</td> </tr> <tr> <td>Genotype 1a, with cirrhosis</td> <td>Sovaldi® + Olysio® +/- ribavirin</td> <td>24 weeks</td> </tr> <tr> <td>Genotype 1b, without cirrhosis</td> <td>Sovaldi® + Olysio®</td> <td>12 weeks</td> </tr> <tr> <td>Genotype 1b, with cirrhosis</td> <td>Sovaldi® + Olysio®</td> <td>24 weeks</td> </tr> <tr> <td>Genotype 1, Olysio® ineligible</td> <td>Sovaldi® + peginterferon alfa + ribavirin</td> <td>12 weeks</td> </tr> <tr> <td>Genotype 1, Olysio® and peginterferon ineligible</td> <td>Sovaldi® + ribavirin</td> <td>24 weeks</td> </tr> <tr> <td>Genotype 2</td> <td>Sovaldi® + ribavirin</td> <td>12 weeks</td> </tr> </tbody> </table>	Patient Characteristics	Treatment	Authorization Duration	Genotype 1a, without cirrhosis	Sovaldi® + Olysio® +/- ribavirin	12 weeks	Genotype 1a, with cirrhosis	Sovaldi® + Olysio® +/- ribavirin	24 weeks	Genotype 1b, without cirrhosis	Sovaldi® + Olysio®	12 weeks	Genotype 1b, with cirrhosis	Sovaldi® + Olysio®	24 weeks	Genotype 1, Olysio® ineligible	Sovaldi® + peginterferon alfa + ribavirin	12 weeks	Genotype 1, Olysio® and peginterferon ineligible	Sovaldi® + ribavirin	24 weeks	Genotype 2	Sovaldi® + ribavirin	12 weeks
Patient Characteristics	Treatment	Authorization Duration																							
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Genotype 1, Olysio® and peginterferon ineligible	Sovaldi® + ribavirin	24 weeks																							
Genotype 2	Sovaldi® + ribavirin	12 weeks																							

Genotypes 3, 4, 5, or 6	Sovaldi® + peginterferon alfa + ribavirin	12 weeks
Genotype 3 or 4, peginterferon ineligible	Sovaldi® + ribavirin	24 weeks
Hepatocellular Carcinoma Awaiting Liver Transplantation	Sovaldi® + ribavirin	Up to 48 weeks (or until liver transplantation, whichever occurs first)

to:

Patient Characteristics		Sovaldi® Authorization Information	
Genotype, Other Features	Hepatitis C Treatment History	Treatment	Authorization Duration
1a, without cirrhosis	Treatment-naïve/ Treatment- experienced	Sovaldi® + Olysio® +/- ribavirin	12 weeks
1a, with cirrhosis	Treatment-naïve/ Treatment- experienced	Sovaldi® + Olysio® +/- ribavirin	24 weeks
1b, without cirrhosis	Treatment-naïve	Sovaldi® + Olysio®	12 weeks
1b, without cirrhosis	Treatment- experienced	Sovaldi® + Olysio® +/- ribavirin	12 weeks
1b, with cirrhosis	Treatment-naïve	Sovaldi® + Olysio®	24 weeks
1b, with cirrhosis	Treatment- experienced	Sovaldi® + Olysio® +/- ribavirin	24 weeks
2	Treatment-naïve	Sovaldi® + ribavirin	12 weeks
2	Treatment- experienced	Sovaldi® + ribavirin	12 weeks to 16 weeks
2	Treatment- experienced	Sovaldi® + peginterferon alfa + ribavirin	12 weeks

	<table border="1"> <tr> <td data-bbox="451 258 683 373">3, 4, 5, or 6</td> <td data-bbox="683 258 954 373">Treatment-naive/ Treatment-experienced</td> <td data-bbox="954 258 1206 373">Sovaldi® + peginterferon alfa + ribavirin</td> <td data-bbox="1206 258 1494 373">12 weeks</td> </tr> <tr> <td data-bbox="451 373 683 554">3 or 4</td> <td data-bbox="683 373 954 554">Treatment-naive/ Treatment-experienced, peginterferon ineligible</td> <td data-bbox="954 373 1206 554">Sovaldi® + ribavirin</td> <td data-bbox="1206 373 1494 554">24 weeks</td> </tr> <tr> <td colspan="2" data-bbox="451 554 954 768">Hepatocellular Carcinoma Awaiting Liver Transplantation</td> <td data-bbox="954 554 1206 768">Sovaldi® + ribavirin</td> <td data-bbox="1206 554 1494 768">Up to 48 weeks (or until liver transplantation, whichever occurs first)</td> </tr> </table>	3, 4, 5, or 6	Treatment-naive/ Treatment-experienced	Sovaldi® + peginterferon alfa + ribavirin	12 weeks	3 or 4	Treatment-naive/ Treatment-experienced, peginterferon ineligible	Sovaldi® + ribavirin	24 weeks	Hepatocellular Carcinoma Awaiting Liver Transplantation		Sovaldi® + ribavirin	Up to 48 weeks (or until liver transplantation, whichever occurs first)
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Hepatocellular Carcinoma Awaiting Liver Transplantation		Sovaldi® + ribavirin	Up to 48 weeks (or until liver transplantation, whichever occurs first)										
11/20/2014	<p>1. Changed Prior Authorization Criteria from:</p> <p>“I. Documented diagnosis of Chronic Hepatitis C (CHC) Infection with confirmed genotype 1, 2, 3, 4, 5, or 6, including those with hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation) and those with HCV/HIV-1 co-infection; II. Documented Metavir score of F3 or F4; III. Must be used in combination with ONE of the following treatments A, B, or C: A. Peginterferon alfa and ribavirin if genotype 1, 4, 5, or 6; B. Ribavirin if genotype 1 when the patient is peginterferon ineligible (i.e. the patient is intolerant to or has a contraindication to peginterferon); C. Ribavirin if genotype 2 or 3; IV. Minimum age requirement: 18 years old; V. Genotype 1 patients who are able to use peginterferon, must have a documented failure, intolerance, or contraindication to a protease inhibitor (i.e. Incivek®, Olysio™, or Victrelis®); VI. Prescriber is a Gastroenterologist, Infectious Disease Specialist, or Hepatologist”</p> <p>to:</p> <p>“I. Documented diagnosis of one of the following conditions A or B AND must meet criteria listed under applicable diagnosis: A. Chronic Hepatitis C (CHC) Infection with confirmed genotypes 1, 2, 3, 4, 5, or 6 and criteria 1 and 2 are met: 1. Documentation that member meets ONE of the following criteria a, b, or c: a. Has a Metavir score of F3 (advanced fibrosis) or F4 (compensated cirrhosis); b. Is post-liver transplant; c. Has serious extrahepatic manifestations of hepatitis C infection; 2. Sovaldi® must be used in combination with ONE of the following regimens a through d: a. Peginterferon alfa and ribavirin for genotypes 1, 4, 5, or 6; b. Ribavirin for genotype 1 AND criterion i is met: i. Member is peginterferon ineligible (i.e. the patient is intolerant to or has a contraindication to peginterferon); c. Olysio® for genotype 1 AND criteria i and ii are met: i. Member is peginterferon ineligible (i.e. the patient is intolerant to or has a contraindication to peginterferon); ii. Member has a documented intolerance, contraindication to, or does not meet Prior Authorization Criteria for Harvoni®; d. Ribavirin for genotypes 2 or 3; B. Hepatocellular carcinoma and criteria 1 and 2 are met: 1. The member is awaiting liver transplantation; 2. Sovaldi® must be used in combination with ribavirin; II. Minimum age requirement: 18 years old; III. Prescriber is a Gastroenterologist, Infectious Disease Specialist, or Hepatologist”.</p>												

	<p>2. Changed Exclusion Criteria from "N/A" to "As retreatment when there has been relapse after, or no response to, a prior treatment course with Harvoni® (ledipasvir/sofosbuvir), Incivek® (telaprevir), Olysio® (simeprevir), Sovaldi® (sofosbuvir), or Victrelis® (boceprevir); Coadministered of Sovaldi® with any of drugs listed in the table below:</p> <table border="1" data-bbox="451 422 1382 690"> <thead> <tr> <th>Drug Class</th> <th>Drugs within class</th> </tr> </thead> <tbody> <tr> <td>Anticonvulsants</td> <td>Carbamazepine, oxcarbazepine, phenobarbital, phenytoin</td> </tr> <tr> <td>Antimycobacterials</td> <td>Rifabutin rifampin rifapentine</td> </tr> <tr> <td>Herbal Supplements</td> <td>St. John's wort (<i>Hypericum perforatum</i>)</td> </tr> <tr> <td>HIV Protease Inhibitors</td> <td>Tipranavir/ritonavir</td> </tr> </tbody> </table> <p>3. Changed "30 tablets per 30 days" to "28 tablets per 28 days" under the Quantity/Days Supply Restrictions section.</p> <p>4. Added the following two rows to the table under the Approval Length section:</p> <table border="1" data-bbox="461 835 1404 1083"> <thead> <tr> <th>Patient Characteristics</th> <th>Treatment</th> <th>Authorization Duration</th> </tr> </thead> <tbody> <tr> <td>Genotype 1 CHC without cirrhosis</td> <td>Sovaldi® + Olysio®</td> <td>12 weeks</td> </tr> <tr> <td>Genotype 1 CHC with cirrhosis</td> <td>Sovaldi® + Olysio®</td> <td>24 weeks</td> </tr> </tbody> </table> <p>– Added "http://blue.regence.com/trgmedpol/drugs/dru332b.pdf" and "http://www.olsio.com/shared/product/olsio/prescribing-information.pdf" to References section.</p>	Drug Class	Drugs within class	Anticonvulsants	Carbamazepine, oxcarbazepine, phenobarbital, phenytoin	Antimycobacterials	Rifabutin rifampin rifapentine	Herbal Supplements	St. John's wort (<i>Hypericum perforatum</i>)	HIV Protease Inhibitors	Tipranavir/ritonavir	Patient Characteristics	Treatment	Authorization Duration	Genotype 1 CHC without cirrhosis	Sovaldi® + Olysio®	12 weeks	Genotype 1 CHC with cirrhosis	Sovaldi® + Olysio®	24 weeks
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<p>6/30/2014</p>	<p>1. Changed Sovaldi™ to Sovaldi®.</p> <p>2. Added information for Genotypes 5 and 6 to "Prior Authorization Criteria" and "Approval Length" sections.</p> <p>3. Added "Documented Metavir score of F3 or F4" requirement to Prior Authorization Criteria section.</p> <ul style="list-style-type: none"> Updated references to include AASLD/IDSA guidelines. 																			

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.