MEDICATION POLICY

Generic Name: Sofosbuvir

Therapeutic Class or Brand Name: Sovaldi®

Applicable Drugs (if Therapeutic Class)**:** N/A

Date of Origin: 2/11/14 **Date Last Reviewed/Revised:** 8/12/16

GPI Code: 1235308000

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. Chronic Hepatitis C (CHC) Infection with confirmed genotypes 1, 2, 3, or 4 AND criteria 1 and 2 are met:

1. Documentation that patient 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.
2. 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™ and Epclusa®.
      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.

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.

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®.

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.

2) Patient has a documented intolerance or contraindication to ribavirin.

B. Hepatocellular carcinoma and criterion 1 is met:

1. The patient is awaiting liver transplantation.

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. Minimum age requirement: 18 years old.

V. 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 Daklinza® (daclatasvir), Epclusa® (sofosbuvir/velpatasvir), Harvoni® (ledipasvir/sofosbuvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir), or Zepatier™ (elbasvir/grazoprevir).
- Child-Pugh C.
- 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 (*Hypericum perforatum*)
HIV Protease Inhibitors	Tipranavir/ritonavir
Other polymerase inhibitors used to treat chronic hepatitis C virus infection	Epclusa® (sofosbuvir/velpatasvir), Harvoni® (ledipasvir/sofosbuvir), Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir)

Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- 28 tablets per 28 days.

Approval Length:

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

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

Table 1. Authorization information for Genotypes 1 through 4.

		Authorization Duration									
Drug Therapy	**Cirrhosis**	**G1a**		**G1b**		**G2**		**G3**		**G4**	
		TN	**TE**	**TN**	**TE**	**TN**	**TE**	**TN**	**TE**	**TN**	**TE**

[n]Only for patients who have tested negative for the Q80K variant.
[^]For patients who develop HCV infection post-liver transplantation.
[1]For patients who have failed pegIFN/RBV.
[2]For patients who have failed sofosbuvir + RBV.
[5]For 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

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

Appendix:

N/A

References:

1. http://hcvguidelines.org/full-report-view.
2. http://www.bcbsnc.com/assets/services/public/pdfs/formulary/sovaldi_um_2015_criteria.pdf.
3. http://blue.regence.com/trgmedpol/drugs/dru332b.pdf.
4. Medi-Span.
5. http://www.gilead.com/~/media/Files/pdfs/medicines/liver-disease/sovaldi/sovaldi_pi.pdf.
6. http://www.olysio.com/shared/product/olysio/prescribing-information.pdf.
7. http://packageinserts.bms.com/pi/pi_daklinza.pdf.
8. http://www.fda.gov/Drugs/DrugSafety/ucm439484.htm.
9. http://www.merck.ca/assets/en/pdf/products/ZEPATIER-PM_E.pdf.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
8/12/2016	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

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"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.

		Authorization Duration							
Drug Therapy	**Cirrhosis**	**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[1,2]
	Comp						12w[1,2]	12w	12w[1,2]
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]

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	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

[n]Only for patients who have tested negative for the Q80K variant.

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

[1]For 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.

[2]For patients who have failed sofosbuvir + RBV.

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

Table 2. Authorization information for Genotypes 4 through 6.

		Authorization Duration					
Drug Therapy	**Cirrhosis**	**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					
Daklinza® + Sovaldi® + RBV	No						
	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.

[1]For patients who have failed pegIFN/RBV.

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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.

		Authorization Duration									
Drug Therapy	**Cirrhosis**	**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;

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	RBV = ribavirin; pegIFN = peginterferon; w = weeks [n]Only for patients who have tested negative for the Q80K variant. [^]For patients who develop HCV infection post-liver transplantation. [1]For patients who have failed pegIFN/RBV. [2]For patients who have failed sofosbuvir + RBV. [5]For 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 14. **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 l 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

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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		Sovaldi® + ribavirin + peginterferon	**12 weeks**

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	Treatment-experienced *(failed peginterferon + ribavirin)*	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® + 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 informaiton for genotypes 4 through 6, and table 3 contains information for hepatocellular carcinoma.

Table 1. Authorization information for Genotypes 1 through 3.

		Authorization Duration							
Drug Therapy	**Cirrhosis**	**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^		
	No						12w[2]	12w	12w[1,2]

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Sovaldi® + pegIFN/RBV	Comp						12w[1,2]	12w	12w[1,2]
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

[n]Only for patients who have tested negative for the Q80K variant.

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

[1]For 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.

[2]For patients who have failed sofosbuvir + RBV.

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

Table 2. Authorization information for Genotypes 4 through 6.

		Authorization Duration					
Drug Therapy	**Cirrhosis**	**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					
		Daklinza™ + Sovaldi® + RBV	No						
			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.
[1]For 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

5. **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 l 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®

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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**

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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**

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			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® + 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)**

on table following Authorization under Approval Length.

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

5/20/2015	1. **Changed** "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 coinfected with HIV-1; e. Is coinfected 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 activities of daily living (i.e. meal preparation, household chores, etc.); h. Has Type 2 diabetes mellitus (insulin resistant); i. Has porphyria cutanea tarda" **to "**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" **under Prior Authorization Criteria**.
4/1/2015	1. **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

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<table>
<tr><td colspan="2">Historical Tracking Of Changes Made To Policy</td></tr>
<tr><td></td><td>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 coinfected with HIV-1; e. Is coinfected 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 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.</td></tr>
<tr><td>3/25/2015</td><td>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.
2. Added “http://www.fda.gov/Drugs/DrugSafety/ucm439484.htm” under References.</td></tr>
<tr><td>2/7/2015</td><td>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.
2. Changed table under Approval Length from:
<table>
<tr><th>Patient Characteristics</th><th>Treatment</th><th>Authorization Duration</th></tr>
<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>
<tr><td>Genotypes 3, 4, 5, or 6</td><td>Sovaldi® + peginterferon alfa + ribavirin</td><td>12 weeks</td></tr>
<tr><td>Genotype 3 or 4, peginterferon ineligible</td><td>Sovaldi® + ribavirin</td><td>24 weeks</td></tr>
</table></td></tr>
</table>

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	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**
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)**

1/28/2015	1. **Changed** "Has serious extrahepatic manifestations of hepatitis C infection" **to** "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" **under Prior Authorization Criteria**. 2. **Changed**:

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"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"
to:
"2. 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®" **under Prior Authorization Criteria**.

3. **Changed** "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)" **to** "Ribavirin 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 contraindication to ALL of the following: Harvoni®, Viekira Pak™, AND Olysio®" **under Prior Authorization Criteria**.
4. **Added** "Documentation of member's Hepatitis C treatment history" **under Prior Authorization Criteria**.
5. **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), or Victrelis® (boceprevir)" **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), Victrelis® (boceprevir), or Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir /dasabuvir)" **under Exclusion Criteria**.
6. **Changed** "Coadministered of Sovaldi® with any of drugs listed in the table below:" **to** "Coadministration of Sovaldi® with any of the drugs listed in the table below:" **under Exclusion Criteria**.
7. **Changed** "Other drugs containing sofosbuvir: Harvoni® (ledipasvir/sofosbuvir)" **to** "Other polymerase inhibitors used to treat chronic hepatitis C virus infection: Harvoni® (ledipasvir/sofosbuvir), Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir /dasabuvir)" **on table for "Coadministration of Sovaldi® with any of the drugs listed in the table below:" under Exclusion Criteria**.
8. **Added** "Other drugs containing sofosbuvir: Harvoni® (ledipasvir/sofosbuvir)" **to the table for "Coadministration of Sovaldi® with any of drugs listed in the table below" under Exclusion Criteria**.
9. **Changed table under Approval Length from:**

Patient Characteristics	Treatment	Authorization Duration
Genotypes 1, 4, 5, or 6 CHC	Sovaldi® + peginterferon alfa + ribavirin	**12 weeks**

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Genotype 1 CHC who are peginterferon ineligible	Sovaldi® + ribavirin	**24 weeks**
Genotype 1 CHC without cirrhosis	Sovaldi® + Olysio®	**12 weeks**
Genotype 1 CHC with cirrhosis	Sovaldi® + Olysio®	**24 weeks**
Genotype 2 CHC	Sovaldi® + ribavirin	**12 weeks**
Genotype 3 CHC	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	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**
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)**

10. **Changed** "http://www.bcbsnc.com/assets/services/public/pdfs/formulary/sofosbuvir_um_criteria.pdf" **to** "http://www.bcbsnc.com/assets/services/public/pdfs/formulary/sovaldi_um_2015_criteria.pdf" **and** "http://www.hcvguidelines.org/sites/default/files/full_report.pdf" **to** "http://www.hcvguidelines.org/fullreport" **under References**.

11/20/2014	1. **Changed Prior Authorization Criteria from:** "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

MEDICATION POLICY

<table>
<tr><td colspan="2">Historical Tracking Of Changes Made To Policy</td></tr>
<tr><td></td><td>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”
to:
“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”.
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:
<table>
<tr><th>Drug Class</th><th>Drugs within class</th></tr>
<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 (Hypericum perforatum)</td></tr>
<tr><td>HIV Protease Inhibitors</td><td>Tipranavir/ritonavir</td></tr>
</table>
”.
3. Changed “30 tablets per 30 days” to “28 tablets per 28 days” under the Quantity/Days Supply Restrictions section.
4. Added the following two rows to the table under the Approval Length section:
<table>
<tr><th>Patient Characteristics</th><th>Treatment</th><th>Authorization Duration</th></tr>
<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>
</table>
5. Added “http://blue.regence.com/trgmedpol/drugs/dru332b.pdf” and “http://www.olysio.com/shared/product/olysio/prescribing-information.pdf” to References section.</td></tr>
<tr><td>6/30/2014</td><td>1. Changed Sovaldi™ to Sovaldi®.
2. Added information for Genotypes 5 and 6 to “Prior Authorization Criteria” and “Approval Length” sections.
3. Added “Documented Metavir score of F3 or F4” requirement to Prior Authorization Criteria section.
4. Updated references to include AASLD/IDSA guidelines.</td></tr>
</table>