MEDICATION POLICY

Generic Name: Ribavirin

Therapeutic Class or Brand Name: Ribavirin

Applicable Drugs (if Therapeutic Class)**:**

Preferred: Ribavirin (generic)

Non-Preferred: Copegus®, Moderiba™, Rebetol®, Ribasphere®

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 8/12/16

GPI Code: 1235307000

Prior Authorization Criteria (may be considered medically necessary when criteria I through VI 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 criterion 1 is 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.
   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: 3 years old.

V. Prescriber is a Gastroenterologist, Infectious Disease Specialist, or Hepatologist.

VI. Non-preferred products (i.e. Copegus®, Moderiba™, Rebetol®, Ribasphere®) require a documented clinical reason containing details as to why generic ribavirin is not appropriate or is contraindicated.

Exclusion Criteria:

- Pregnant women and men whose female partners are pregnant.
- Hemoglobinopathies.
- Coadministration with didanosine.

Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- Quantities of up to 180 tablets or capsules per 30 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	G1a		G1b		G2		G3		G4	
		TN	TE	TN	TE	TN	TE	TN	TE	TN	TE
Zepatier™ + RBV	No	16w[t]	12-16w[p4], 16w[t1]		12w[4]						16w[1b]
	Comp	16w[t]	12-16w[p4], 16w[t1]		12w[4]						16w[1b]
Epclusa® + RBV	No						12w[2]		12w[2]		
	Comp						12w[2]		12w[1,2]		
	Decomp	12w	12w	12w	12w	12w	12w	12w	12w	12w	12w
Viekira Pak™/XR™ + RBV	No	12w	12w[1]								
	No & Post Transplant[^]	24w[^]		24w[^]							
	Comp	24w	24w[1]								
Technivie™+ RBV	No									12w	12w[1]
	Comp									12w	12w[1]

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Table 1. Authorization information for Genotypes 1 through 4.

Drug Therapy	Cirrhosis	G1a		G1b		G2		G3		G4	
		TN	TE	TN	TE	TN	TE	TN	TE	TN	TE
Harvoni® + RBV	No		12w[3]		12w[3]						
	No & Post Transplant[^]	12w[^]	12w[^]	12w[^]	12w[^]					12w[^]	12w[^]
	Comp		12w[5], 24w[3]		12w[5], 24w[3]						12w[1]
	Comp & Post Transplant[^]	12w[^]	12w[^]	12w[^]	12w[^]					12w[^]	12w[^]
	Decomp	12w	12w[5]	12w	12w[5]					12w	12w
	Decomp & Post Transplant[^]	12w[^]	12w[^]	12w[^]	12w[^]					12w[^]	12w[^]
Sovaldi® + RBV	No & Post Transplant[^]					24w[^]	24w[^]				
	Comp & Post Transplant[^]					24w[^]	24w[^]				
	Decomp & Post Transplant[^]					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

[t]For genotype 1a, Zepatier™ should be given alone for 12 weeks in patients without, or with ribavirin for 16 weeks in patients with, NS5A resistance-associated polymorphisms at amino acid positions 28, 30, 31, or 93.

[p]Patients who have NS5A resistance-associated polymorphisms at amino acid positions 28, 30, 31, or 93 should have treatment extended to 16 weeks.

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

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

[1b]For patients who experienced on-treatment virologic failure while on prior pegIFN/RBV therapy.

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

[3]For patients who have failed sofosbuvir + RBV +/- pegIFN.

[4]For patients who have failed a NS3 protease inhibitor + pegIFN/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.fchp.org/~/media/Files/FCHP/Imported/Copegus_ribavirin.pdf.ashx.
3. Medi-Span.
4. http://www.merck.com/product/usa/pi_circulars/r/rebetol/rebetol_pi.pdf.
5. http://www.gene.com/download/pdf/copegus_prescribing.pdf.
6. http://kadmon.com/files/ribasphere-tablets-pi.pdf.
7. http://rxabbvie.com/pdf/moderiba_PI.pdf.

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Historical Tracking Of Changes Made To Policy

8/12/2016

1. **Changed** "I. A. Chronic Hepatitis C (CHC) Infection with confirmed genotypes 1, 2, 3, 4, 5, or 6 AND…" **to** "Chronic Hepatitis C (CHC) Infection with confirmed genotypes 1, 2, 3, or 4 AND…" **under Prior Authorization Criteria**.
2. **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**.
3. **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 Information							
		G1a		G1b		G2		G3	
		TN	TE	TN	TE	TN	TE	TN	TE
Zepatier™ + RBV	No	16w[t]	12w[t5], 16w[t5]		12w[5]				
	Comp	16w[t]	12w[t4], 16w[t5]		12w[4]				
Viekira Pak™ + RBV	No	12w	12w[1]						
	No & Post Transplant[^]	24w[^]		24w[^]					
	Comp	24w	24w[1]						
Technivie™+ RBV	No								
	Comp								
Harvoni® + RBV	No		12w[3]		12w[3]				
	No & Post Transplant[^]	12w[^]	12w[^]	12w[^]	12w[^]				
	Comp		12w[5], 24w[3]		12w[5], 24w[3]				
	Comp & Post Transplant[^]	12w[^]	12w[^]	12w[^]	12w[^]				
	Decomp	12w	12w[5], 24w[6]	12w	12w[5], 24w[6]				
	Decomp & Post Transplant[^]	12w[^]	12w[^]	12w[^]	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[^]

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 judgment in providing the most appropriate care for their patients.

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	Decomp & Post Transplant^					24w^	24w^		
Sovaldi® + pegIFN/RBV	No						12w[2]	12w	12w[1,2]
	Comp						12w[1,2]	12w	12w[1,2]
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
[t]For genotype 1a, Zepatier™ should be given alone for 12 weeks in patients without, or with ribavirin for 16 weeks in patients with, NS5A resistance-associated polymorphisms at amino acid positions 28, 30, 31, or 93.
^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.
[3]For patients who have failed sofosbuvir + RBV +/- pegIFN.
[4]For patients who have failed a NS3 protease inhibitor + pegIFN/RBV.
[5]For patients who have failed pegIFN/RBV +/- a NS3 protease inhibitor.
[6]For patients who have failed a sofosbuvir-based treatment.

Table 2. Authorization information for Genotypes 4 through 6.

Drug Therapy	**Cirrhosis**	**Authorization Duration**					
		G4		**G5**		**G6**	
		TN	**TE**	**TN**	**TE**	**TN**	**TE**
Zepatier™ + RBV	No		16w[1b]				
	Comp		16w[1b]				
Viekira Pak™ + RBV	No						
	No & Post Transplant^						
	Comp						
Technivie™+ RBV	No	12w	12w[1]				
	Comp	12w	12w[1]				
Harvoni® + RBV	No						
	No & Post Transplant^	12w^	12w^				
	Comp		12w[1]				
	Comp & Post Transplant^	12w^	12w^				
	Decomp	12w	24w[6]				

Historical Tracking Of Changes Made To Policy

	Decomp & Post Transplant^	12w^	12w^				
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® + 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.
[1b]For patients who experienced on-treatment virologic failure while on prior pegIFN/RBV therapy.
[6]For patients who have failed a sofosbuvir-based treatment.

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	G1a		G1b		G2		G3		G4	
		TN	TE	TN	TE	TN	TE	TN	TE	TN	TE
Zepatier™ + RBV	No	16w[t]	12-16w[p4], 16w[t1]		12w[4]						16w[1b]
	Comp	16w[t]	12-16w[p4], 16w[t1]		12w[4]						16w[1b]
Epclusa® + RBV	No						12w[2]		12w[2]		
	Comp						12w[2]		12w[1,2]		
	Decomp	12w	12w	12w	12w	12w	12w	12w	12w	12w	12w

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Viekira Pak™/XR™ + RBV	No	12w	12w[1]								
	No & Post Transplant^	24w^		24w^							
	Comp	24w	24w[1]								
Technivie™+ RBV	No									12w	12w[1]
	Comp									12w	12w[1]
Harvoni® + RBV	No		12w[3]		12w[3]						
	No & Post Transplant^	12w^	12w^	12w^	12w^					12w^	12w^
	Comp		12w[5], 24w[3]		12w[5], 24w[3]						12w[1]
	Comp & Post Transplant^	12w^	12w^	12w^	12w^					12w^	12w^
	Decomp	12w	12w[5]	12w	12w[5]					12w	12w
	Decomp & Post Transplant^	12w^	12w^	12w^	12w^					12w^	12w^
Sovaldi® + RBV	No & Post Transplant^					24w^	24w^				
	Comp & Post Transplant^					24w^	24w^				
	Decomp & Post Transplant^					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
[t]For genotype 1a, Zepatier™ should be given alone for 12 weeks in patients without, or with ribavirin for 16 weeks in patients with, NS5A resistance-associated polymorphisms at amino acid positions 28, 30, 31, or 93.
[p]Patients who have NS5A resistance-associated polymorphisms at amino acid positions 28, 30, 31, or 93 should have treatment extended to 16 weeks.
^For patients who develop HCV infection post-liver transplantation.
[1]For patients who have failed pegIFN/RBV.
[1b]For patients who experienced on-treatment virologic failure while on prior pegIFN/RBV therapy.
[2]For patients who have failed sofosbuvir + RBV.
[3]For patients who have failed sofosbuvir + RBV +/- pegIFN.
[4]For patients who have failed a NS3 protease inhibitor + pegIFN/RBV.

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	[5]For patients who have failed pegIFN/RBV +/- a NS3 protease inhibitor. **Table 2. Authorization Information for Hepatocellular Carcinoma.** RBV = ribavirin

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

3/21/2016	1. **Changed** "member" **to** "patient" **throughout policy**. 2. **Changed** "A. Chronic Hepatitis C (CHC) Infection with confirmed genotypes 1, 2, 3, 4, 5, or 6 AND criteria 1 and 2 are met: …" **to** "A. Chronic Hepatitis C (CHC) Infection with confirmed genotypes 1, 2, 3, 4, 5, or 6 AND criterion 1 is met:…" and removed "2. Ribavirin must be used in combination with ONE of the following regimens a through l AND member must meet criteria listed with applicable regimen: a. Viekira Pak™ for genotype 1a AND criterion i is met: i. Member is treatment-naïve or has failed treatment with peginterferon + ribavirin; b. Viekira Pak™ for genotype 1a or 1b if member is a liver transplant recipient; c. Harvoni® for genotype 1 in members who have failed one of the following treatments i through iii: i. Peginterferon + ribavirin +/- protease inhibitor; ii. Sovaldi® + ribavirin +/- peginterferon; iii. Olysio® + Sovaldi®; d. Sovaldi® for genotype 2 and criterion i is met: i. Member is treatment-naïve or has failed treatment with peginterferon + ribavirin; e. Sovaldi® + peginterferon for genotype 2 in members who have failed prior treatment with one of the following i or ii: i. Peginterferon + ribavirin; ii. Sovaldi® + ribavirin; f. Sovaldi® + peginterferon 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. Sovaldi® 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. Sovaldi® + Daklinza™ 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. Technivie™ for genotype 4 without cirrhosis; j. Sovaldi® + peginterferon 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. Sovaldi® 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. Sovaldi® + peginterferon for genotypes 5 or 6 AND criterion i is met: i. Member has a documented intolerance or contraindication to Harvoni®" **under Prior Authorization Criteria**. 3. **Changed** "B. Hepatocellular carcinoma and criteria 1 and 2 are met: 1. The member is awaiting liver transplantation; 2. Ribavirin must be used in combination with Sovaldi®" **to** "B. Hepatocellular carcinoma and criterion 1 is met: 1. The patient is awaiting liver transplantation" **under Prior Authorization Criteria**. 4. **Added** "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**. 5. **Changed section following Authorization under Approval Length from:** **Authorization:** See table directly below.

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Patient Characteristics		Authorization Information	
Genotype, Other Features	**Hepatitis C Treatment History**	**Treatment**	**Authorization Duration**
1a, without cirrhosis	Treatment-naïve/ Treatment-experienced	Viekira Pak™ + ribavirin	**12 weeks**
1a, with cirrhosis	Treatment-naïve/ Treatment-experienced	Viekira Pak™ + ribavirin	**24 weeks**
1a or 1b, without cirrhosis	Treatment-experienced *(failed: 1. Sovaldi® + ribavirin +/- peginterferon, OR 2. Olysio® + Sovaldi®)*	Harvoni® + ribavirin	**12 weeks**
1a or 1b, with cirrhosis	Treatment-experienced *(failed peginterferon + ribavirin +/- protease inhibitor)*	Harvoni® + ribavirin	**12 weeks**
1a or 1b, with cirrhosis	Treatment-experienced *(failed: 1. Sovaldi® + ribavirin +/- peginterferon, OR 2. Olysio® + Sovaldi®)*	Harvoni® + ribavirin	**24 weeks**
1a or 1b	Liver Transplant Recipients	Viekira Pak™ + ribavirin	**24 weeks**
2, without cirrhosis	Treatment-naïve	Sovaldi® + ribavirin	**12 weeks**
2, with cirrhosis	Treatment-naïve	Sovaldi® + ribavirin	**16 weeks**
2	Treatment-experienced	Sovaldi® + ribavirin	**16 to 24 weeks**
		Sovaldi® + ribavirin + peginterferon	**12 weeks**
3, without cirrhosis	Treatment-naïve	Sovaldi® + ribavirin + peginterferon	**12 weeks**
		Sovaldi® + ribavirin	**24 weeks**
3, without cirrhosis	Treatment-experienced *(failed peginterferon + ribavirin)*	Sovaldi® + ribavirin + peginterferon	**12 weeks**
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**

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3, with cirrhosis	Treatment-experienced	Sovaldi® + ribavirin + peginterferon	**12 weeks**
		Sovaldi® + Daklinza™ + ribavirin	**24 weeks**
Genotype 4, without cirrhosis	Treatment-naïve/ Treatment-experienced	Technivie™ + ribavirin	**12 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 Information**							
		G1a		**G1b**		**G2**		**G3**	
		TN	**TE**	**TN**	**TE**	**TN**	**TE**	**TN**	**TE**
Zepatier™ + RBV	No	16w[t]	12w[t5], 16w[t5]		12w[5]				
	Comp	16w[t]	12w[t4], 16w[t5]		12w[4]				
Viekira Pak™ + RBV	No	12w	12w[1]						
	No & Post Transplant[^]	24w[^]		24w[^]					
	Comp	24w	24w[1]						
Technivie™+ RBV	No								
	Comp								
Harvoni® + RBV	No		12w[3]		12w[3]				
	No & Post Transplant[^]	12w[^]	12w[^]	12w[^]	12w[^]				
	Comp		12w[5], 24w[3]		12w[5], 24w[3]				
	Comp & Post Transplant[^]	12w[^]	12w[^]	12w[^]	12w[^]				
	Decomp	12w	12w[5], 24w[6]	12w	12w[5], 24w[6]				

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	Decomp & Post Transplant^	12w^	12w^	12w^	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]
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
[t]For genotype 1a, Zepatier™ should be given alone for 12 weeks in patients without, or with ribavirin for 16 weeks in patients with, NS5A resistance-associated polymorphisms at amino acid positions 28, 30, 31, or 93.
^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.
[3]For patients who have failed sofosbuvir + RBV +/- pegIFN.
[4]For patients who have failed a NS3 protease inhibitor + pegIFN/RBV.
[5]For patients who have failed pegIFN/RBV +/- a NS3 protease inhibitor.
[6]For patients who have failed a sofosbuvir-based treatment.

Table 2. Authorization information for Genotypes 4 through 6.

Drug Therapy	**Cirrhosis**	**Authorization Duration**					
		G4		**G5**		**G6**	
		TN	**TE**	**TN**	**TE**	**TN**	**TE**
Zepatier™ + RBV	No		16w[1b]				
	Comp		16w[1b]				
	No						

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Viekira Pak™ + RBV	No & Post Transplant^						
	Comp						
Technivie™+ RBV	No	12w	12w[1]				
	Comp	12w	12w[1]				
Harvoni® + RBV	No						
	No & Post Transplant^	12w^	12w^				
	Comp		12w[1]				
	Comp & Post Transplant^	12w^	12w^				
	Decomp	12w	24w[6]				
	Decomp & Post Transplant^	12w^	12w^				
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® + 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.
[1b]For patients who experienced on-treatment virologic failure while on prior pegIFN/RBV therapy.
[6]For patients who have failed a sofosbuvir-based treatment.

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)

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<table>
<tr><td colspan="2">Historical Tracking Of Changes Made To Policy</td></tr>
<tr><td></td><td>RBV = ribavirin
6. Changed “http://www.hcvguidelines.org/fullreport” to “http://hcvguidelines.org/full-report-view” under References.
7. Removed “http://www.connecticare.com/provider/PDFs/Pharmacy/Ribavirin.pdf” from References because link is no longer valid.</td></tr>
<tr><td>12/7/2015</td><td>1. Changed “2. Ribavirin must be used in combination with ONE of the following regimens a through f: a. Viekira Pak™ for genotype 1a AND criterion i is met: i. Member is treatment-naïve or has failed prior treatment with peginterferon + ribavirin; b. Harvoni® for genotype 1 in treatment-experienced members with cirrhosis; c. Sovaldi® for genotype 2; d. Sovaldi® and peginterferon alfa for genotypes 3, 4, or 5; e. Sovaldi® 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); f. Sovaldi® and peginterferon alfa for genotype 6 and criterion i must be met: i. Member must have a documented contraindication to Harvoni®” to “2. Ribavirin must be used in combination with ONE of the following regimens a through l AND member must meet criteria listed with applicable regimen: a. Viekira Pak™ for genotype 1a AND criterion i is met: i. Member is treatment-naïve or has failed treatment with peginterferon + ribavirin; b. Viekira Pak™ for genotype 1a or 1b if member is a liver transplant recipient; c. Harvoni® for genotype 1 in members who have failed one of the following treatments i through iii: i. Peginterferon + ribavirin +/- protease inhibitor; ii. Sovaldi® + ribavirin +/- peginterferon; iii. Olysio® + Sovaldi®; d. Sovaldi® for genotype 2 and criterion i is met: i. Member is treatment-naïve or has failed treatment with peginterferon + ribavirin; e. Sovaldi® + peginterferon for genotype 2 in members who have failed prior treatment with one of the following i or ii: i. Peginterferon + ribavirin; ii. Sovaldi® + ribavirin; f. Sovaldi® + peginterferon 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. Sovaldi® 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. Sovaldi® + Daklinza™ 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. Technivie™ for genotype 4 without cirrhosis; j. Sovaldi® + peginterferon 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. Sovaldi® 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. Sovaldi® + peginterferon for genotypes 5 or 6 AND criterion i is met: i. Member has a documented intolerance or contraindication to Harvoni®” under Prior Authorization.
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 table from:
<table>
<tr><th colspan="2">Patient Characteristics</th><th colspan="2">Authorization Information</th></tr>
<tr><th>Genotype, Other Features</th><th>Hepatitis C Treatment History</th><th>Treatment</th><th>Authorization Duration</th></tr>
<tr><td>1a, without cirrhosis</td><td>Treatment-naïve/ Treatment-experienced</td><td>Viekira Pak™ + ribavirin</td><td>12 weeks</td></tr>
</table>
</td></tr>
</table>

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1a, with cirrhosis	Treatment-naïve/ Treatment-experienced	Viekira Pak™ + ribavirin	**24 weeks**
1b, with cirrhosis	Treatment-naïve/ Treatment-experienced	Viekira Pak™ + ribavirin	**12 weeks**
1a or 1b, with cirrhosis	Treatment-experienced	Harvoni® + ribavirin	**12 weeks**
1a or 1b	Liver Transplant Recipients	Viekira Pak™ + ribavirin	**24 weeks**
2	Treatment-naïve	Sovaldi® + ribavirin	**12 weeks**
2	Treatment-experienced	Sovaldi® + ribavirin	**12 weeks to 16 weeks**
		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**
4	Treatment-naïve/ Treatment-experienced	Viekira Pak™ + ribavirin	**12 weeks**
5	Treatment-naïve/ Treatment-experienced	peginterferon alfa + ribavirin	**48 weeks**
Hepatocellular Carcinoma Awaiting Liver Transplantation		Sovaldi® + ribavirin	**Up to 48 weeks (or until liver transplantation, whichever occurs first)**

to:

Patient Characteristics		**Authorization Information**	
Genotype, Other Features	**Hepatitis C Treatment History**	**Treatment**	**Authorization Duration**
1a, without cirrhosis	Treatment-naïve/ Treatment-experienced	Viekira Pak™ + ribavirin	**12 weeks**
1a, with cirrhosis	Treatment-naïve/ Treatment-experienced	Viekira Pak™ + ribavirin	**24 weeks**
1a or 1b, without cirrhosis	Treatment-experienced *(failed: 1. Sovaldi® + ribavirin +/- peginterferon, OR 2. Olysio® + Sovaldi®)*	Harvoni® + ribavirin	**12 weeks**

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		1a or 1b, with cirrhosis	Treatment-experienced *(failed peginterferon + ribavirin +/- protease inhibitor)*	Harvoni® + ribavirin	**12 weeks**
		1a or 1b, with cirrhosis	Treatment-experienced *(failed: 1. Sovaldi® + ribavirin +/- peginterferon, OR 2. Olysio® + Sovaldi®)*	Harvoni® + ribavirin	**24 weeks**
		1a or 1b	Liver Transplant Recipients	Viekira Pak™ + ribavirin	**24 weeks**
		2, without cirrhosis	Treatment-naïve	Sovaldi® + ribavirin	**12 weeks**
		2, with cirrhosis	Treatment-naïve	Sovaldi® + ribavirin	**16 weeks**
		2	Treatment-experienced	Sovaldi® + ribavirin	**16 to 24 weeks**
				Sovaldi® + ribavirin + peginterferon	**12 weeks**
		3, without cirrhosis	Treatment-naïve	Sovaldi® + ribavirin + peginterferon	**12 weeks**
				Sovaldi® + ribavirin	**24 weeks**
		3, without cirrhosis	Treatment-experienced *(failed peginterferon + ribavirin)*	Sovaldi® + ribavirin + peginterferon	**12 weeks**
		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**
		3, with cirrhosis	Treatment-experienced	Sovaldi® + ribavirin + peginterferon	**12 weeks**
				Sovaldi® + Daklinza™ + ribavirin	**24 weeks**

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		4	Treatment-naïve/ Treatment-experienced	Sovaldi® + ribavirin + peginterferon	**12 weeks**
				Sovaldi® + ribavirin	**24 weeks**
		Genotype 4, without cirrhosis	Treatment-naïve/ Treatment-experienced	Technivie™ + ribavirin	**12 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)**
	following Authorization under Approval Length.				
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); 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); 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 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**. 2. **Changed** "1. Ribavirin must be used in combination with ONE of the following regimens a through f: a. Viekira Pak™ for genotype 1" **to** "1. Ribavirin must be used in combination with ONE of the following regimens a through f: a. Viekira Pak™ for genotypes 1 or 4" **under Prior Authorization Criteria**.				

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	3. **Added** "4: Treatment-naïve/Treatment-experienced: Viekira Pak™ + ribavirin: 12 weeks" for Genotype, Other Features: Hepatitis C Treatment History: Treatment: Authorization Duration **on table under Approval Length**.
2/13/2015	1. **Removed** "Sovaldi® + Olysio® +/- ribavirin" **information from table under Authorization under Approval Length.**
2/12/2015	1. **Changed** "Preferred: Ribavirin (generic), Rebetol®; Non-Preferred: Copegus®, Ribasphere®" **to** "Ribavirin" **under Therapeutic Class or Brand Name**. 2. **Changed** "N/A" **to** "Preferred: Ribavirin (generic); Non-Preferred: Copegus®, Moderiba™, Rebetol®, Ribasphere®" **under Applicable Drugs (if Therapeutic Class)**. 3. **Changed Prior Authorization Criteria from:** "I. Clinically diagnosed Hepatitis C with detectable serum HCV RNA levels; II. Must be used in combination with peginterferon alfa-2a or interferon alpha-2b; III. Liver biopsy results are obtained unless liver biopsy is contraindicated or there is documentation of compensated cirrhosis based on imaging studies; IV. If patient meets criteria, ribavirin 200 mg tablets or capsules will only be approved. Other dosage forms may be approved if the generic form of ribavirin is contraindicated; V. Minimum age requirement: 3 years old; 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 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. Ribavirin must be used in combination with ONE of the following regimens a through f: a. Viekira Pak™ for genotype 1; b. Harvoni® for genotype 1 in treatment-experienced members with cirrhosis; c. Sovaldi® for genotype 2; d. Sovaldi® and peginterferon alfa for genotypes 3, 4, or 5; e. Sovaldi® 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); f. Sovaldi® and peginterferon alfa for genotype 6 and criterion i must be met: i. Member must have a documented contraindication to Harvoni®; B. Hepatocellular carcinoma and criteria 1 and 2 are met: 1. The member is awaiting liver transplantation; 2. Ribavirin must be used in combination with Sovaldi®; II. Documentation of member's Hepatitis C treatment history; III. Minimum age requirement: 3 years old; IV. Prescriber is a Gastroenterologist, Infectious Disease Specialist, or Hepatologist; V. Non-preferred products (i.e. Copegus®, Moderiba™, Rebetol®, Ribasphere®) require a documented clinical reason containing details as to why generic ribavirin is not appropriate or is contraindicated". 4. **Removed** "Autoimmune hepatitis" **from Exclusion Criteria**. 5. **Changed** "Quantities of up to 210 tablets or capsules per 30 days" **to** "Quantities of up to 180 tablets or capsules per 30 days" **under Quantity/Days Supply Restrictions**. 6. **Changed Authorization under Approval Length from** "One 24 week supply" **to** "See table directly below". 7. **Added the following table under Authorization under Approval Length:**

Patient Characteristics		**Authorization Information**	
Genotype, Other Features	**Hepatitis C Treatment History**	**Treatment**	**Authorization Duration**
1a, without cirrhosis	Treatment-naïve/ Treatment-experienced	Viekira Pak™ + ribavirin	**12 weeks**

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			Sovaldi® + Olysio® +/- ribavirin	**12 weeks**
	1a, with cirrhosis	Treatment-naïve/ Treatment-experienced	Viekira Pak™ + ribavirin	**24 weeks**
			Sovaldi® + Olysio® +/- ribavirin	**24 weeks**
	1b, without cirrhosis	Treatment-experienced	Sovaldi® + Olysio® +/- ribavirin	**12 weeks**
	1b, with cirrhosis	Treatment-naïve/ Treatment-experienced	Viekira Pak™ + ribavirin	**12 weeks**
		Treatment-experienced	Sovaldi® + Olysio® +/- ribavirin	**24 weeks**
	1a or 1b, with cirrhosis	Treatment-experienced	Harvoni® + ribavirin	**12 weeks**
	1a or 1b	Liver Transplant Recipients	Viekira Pak™ + ribavirin	**24 weeks**
	2	Treatment-naïve	Sovaldi® + ribavirin	**12 weeks**
	2	Treatment-experienced	Sovaldi® + ribavirin	**12 weeks to 16 weeks**
			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)**
	8. **Changed Re-Authorization under Approval Length from** "Coverage may be extended for an additional 24 weeks if patient has HCV genotype 1 or 4 AND HCV RNA levels are undetectable after 24 weeks of treatment" **to** "N/A". 9. **Added "**http://www.hcvguidelines.org/fullreport" and "http://rxabbvie.com/pdf/moderiba_PI.pdf" **under References**.			
12/27/2013	1. **Adapted policy to new format.** 2. **Added GPI code**. 3. **Added the following to Exclusion Criteria**: "Pregnant women and men whose female partners are pregnant"; "Hemoglobinopathies"; "Coadministration with didanosine"; "Autoimmune hepatitis". 4. **Changed Quantity/Days Supply Restrictions from** "210 capsules per 30 days" **to** "Quantities of up to 210 tablets or capsules per 30 days". 5. **Updated references** to include Medi-Span and package inserts.			