Generic Name: Ribavirin

Therapeutic Class or Brand Name: Ribavirin

Applicable Drugs (if Therapeutic Class): Copegus®, Moderiba™, Rebetol®, Ribasphere®, Ribavirin (generic).

GPI Code: 1235307000

Preferred: Ribavirin (generic)

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

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 9/10/2019

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:
            (1) Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (i.e. vasculitis).
            (2) 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 6, and table 2 contains information for hepatocellular carcinoma.

Table 1. Authorization information for Genotypes 1 through 6.

Drug Therapy	Cirrhosis	G1a		G1b		G2		G3		G4		G5		G6	
		TN	TE	TN	TE	TN	TE	TN	TE	TN	TE	TN	TE	TN	TE
Zepatier™ + RBV	No	16w[†]	12-16w[p4], 16w[†1]		12w[4]						16w[1b]				
	Comp	16w[†]	12-16w[p4], 16w[†1]		12w[4]						16w[1b]				
Epclusa® + RBV	No								12w[1~]						
	Comp							12w[~]	12w[1]						
	Comp & Post Transplant^					12w^	12w^	12w^	12w^						
	Decomp	12w	12w[5], 24w[10]	12w	12w[5], 24w[10]	12w	12w[5], 24w[10]	12w	12w[5], 24w[10]	12w	12w[5], 24w[10]	12w	12w[5], 24w[10]	12w	12w[5], 24w[10]
	Decomp & Post Transplant^					12w^	12w^	12w^	12w^						
Vosevi® + RBV	No														
	Comp								12w[8]						
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[9x]		12w[9x]										
	No & Post Transplant^	12w^	12w^	12w^	12w^					12w^	12w^	12w^	12w^	12w^	12w^
	Comp		12w[5]		12w[5]						12w[1]				

Drug Therapy	Cirrhosis	G1a		G1b		G2		G3		G4		G5		G6	
		TN	TE	TN	TE	TN	TE	TN	TE	TN	TE	TN	TE	TN	TE
	Comp & Post Transplant^	12w^	12w^	12w^	12w^					12w^	12w^	12w^	12w^	12w^	12w^
	Decomp	12w	24w[11]	12w	24w[11]					12w	24w[11]	12w	24w[11]	12w	24w[11]
	Decomp & Post Transplant^	12w^	12w^	12w^	12w^					12w^	12w^	12w^	12w^	12w^	12w^
Sovaldi® + RBV	No					12w	12w[1]	24w	24w[1]						
	Comp					12w	12w[1]	24w	24w[1]						
Daklinza® + Sovaldi® + RBV	No														
	No & Post Transplant^	12w^	12w^	12w^	12w^	12w^	12w^	12w^	12w^	12w^	12w^	12w^	12w^	12w^	12w^
	Comp							12w, 24w~							
	Comp & Post Transplant^	12w^	12w^	12w^	12w^	12w^	12w^	12w^	12w^	12w^	12w^	12w^	12w^	12w^	12w^
	Decomp	12w		12w		12w		12w		12w					
	Decomp & Post Transplant^					12w^	12w^	12w^	12w^						

TN = treatment naïve; TE = treatment experienced; Comp = compensated; Decomp = decompensated; RBV = ribavirin; pegIFN = peginterferon; w = weeks
[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.
[x]Except in patients who have failed simeprevir.
~RAS testing for Y93H is recommended. If present, ribavirin should be added to the regimen.
^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.
[4]For patients who have failed a NS3 protease inhibitor + pegIFN/RBV.
[5]For patients who have failed pegIFN/RBV +/- a NS3 protease inhibitor.
[8]For patients who have failed a NS5A inhibitor.
[9]For patients who have failed a non-NS5A inhibitor, sofosbuvir-containing regimen.
[10]For patients who failed a sofosbuvir- or NS5A-containing regimen.
[11]For patients who failed a sofosbuvir-based treatment only.

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. Medi-Span®.
3. http://www.merck.com/product/usa/pi_circulars/r/rebetol/rebetol_pi.pdf .
4. http://www.gene.com/download/pdf/copegus_prescribing.pdf .
5. http://kadmon.com/files/ribase-tablets-pi.pdf .
6. http://rxabbvie.com/pdf/moderiba_PI.pdf .

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
9/10/2019	1. **Deleted** item #2 **under References** http://www.fchp.org/~/media/Files/FCHP/Imported/Copegus_ribavirin.pdf.ashx . 2. **Deleted** footnote #1 in Table 1 **under Approval Length** (deletion location noted by red circles):
5/8/2018	1. No change.

Drug Therapy	Cirrhosis	G1a		G1b		G2		G3	
		TN	TE	TN	TE	TN	TE	TN	TE
	Comp & Post Transplant^	12w^	12w^	12w^	12w^				
	Decomp	12w	24w[11]	12w	24w[11]				
	Decomp & Post Transplant^	12w^	12w^	12w^	12w^				
Sovaldi® + RBV	No					12w	12w[1]	24w	24w[1]
	Comp					12w	12w[1]	24w	24w[1]

11/17/2017

1. **Changed** "…Table 1 contains information for genotypes 1 through 4…" **to** "… Table 1 contain information for genotypes 1 through 6…" **following Authorization under Approval Length.**
2. **Changed table 1 below Authorization under Approval Length from (changes made highlighte yellow):**

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[†]	12-16w[p4], 16w[†1]		12w[4]						16w[1b]
	Comp	16w[†]	12-16w[p4], 16w[†1]		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 Transplan †^	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 Transplan †^	12w^	12w^	12w^	12w^					12w^	12w^
	Comp		12w[5], 24w[3]		12w[5], 24w[3]						12w[1]
	Comp & Post Transplan †^	12w^	12w^	12w^	12w^					12w^	12w^
	Decomp	12w	12w[5]	12w	12w[5]					12w	12w
	Decomp & Post Transplan †^	12w^	12w^	12w^	12w^					12w^	12w^
Sovaldi® + RBV	No & Post Transplan †^					24w^	24w^				
	Comp & Post					24w^	24w^				

	Transplan †^										
	Decomp & Post Transplan †^					24w^	24w^				
Daklinza® + Sovaldi® + RBV	No								24w[2]		
	No & Post Transplan †^	12w^	12w^	12w^	12w^	12w^	12w^	12w^	12w^	12w^	12w^
	Comp								24w[1,2]		
	Comp & Post Transplan †^	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.

to:

Table 1. Authorization information for Genotypes 1 through 6.

Drug Therapy	Cirrhosis	G1a		G1b		G2		G3		G4		G5		G6	
		TN	TE	TN	TE	TN	TE	TN	TE	TN	TE	TN	TE	TN	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[1~]						
	Comp							12w[~]	12w[1]						
	Comp & Post					12w^	12w^	12w^	12w^						

	Transplant ^														
	Decomp	12w	12w[5], 24w[10]	12w	12w[5], 24w[10]	12w	12w[5], 24w[10]	12w	12w[5], 24w[10]	12w	12w[5], 24w[10]	12w	12w[5], 24w[10]	12w	12w[5], 24w[10]
	Decomp & Post Transplant ^					12w ^	12w^	12w^	12w^						
Vosevi® + RBV	No														
	Comp								12w[8]						
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[9x]		12w[9x]										
	No & Post Transplant ^	12w ^	12w^	12w ^	12w^					12w ^	12w^	12w^	12w^	12w^	12w^
	Comp		12w[5]		12w[5]						12w[1]				
	Comp & Post Transplant ^	12w ^	12w^	12w ^	12w^					12w ^	12w^	12w^	12w^	12w^	12w^
	Decomp	12w	24w[11]	12w	24w[11]					12w	24w[11]	12w	24w[11]	12w^	24w[11]
	Decomp & Post Transplant ^	12w ^	12w^	12w ^	12w^					12w ^	12w^	12w ^	12w^	12w ^	12w^
Sovaldi® + RBV	No					12w	12w[1]	24w[1]	24w[1]						
	Comp					12w	12w[1]	24w[1]	24w[1]						
Daklinza® + Sovaldi® + RBV	No														
	No & Post Transplant ^	12w ^	12w^	12w ^	12w^	12w ^	12w^	12w^	12w^	12w ^	12w^	12w^	12w^	12w^	12w^
	Comp							12w, 24w ~							
	Comp & Post Transplant ^	12w ^	12w^	12w ^	12w^	12w ^	12w^	12w^	12w^	12w ^	12w^	12w^	12w^	12w^	12w^

	Decomp	12w		12w		12w		12w		12w					
	Decomp & Post Transplant ^					12w ^	12w^	12w^	12w^						

TN = treatment naïve; TE = treatment experienced; Comp = compensated; Decomp = decompensated;
RBV = ribavirin; pegIFN = peginterferon; w = weeks
[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.
[x]Except in patients who have failed simeprevir.
[~]RAS testing for Y93H is recommended. If present, ribavirin should be added to the regimen.
[^]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.
[4]For patients who have failed a NS3 protease inhibitor + pegIFN/RBV.
[5]For patients who have failed pegIFN/RBV +/- a NS3 protease inhibitor.
[8]For patients who have failed a NS5A inhibitor.
[9]For patients who have failed a non-NS5A inhibitor, sofosbuvir-containing regimen.
[10]For patients who failed a sofosbuvir- or NS5A-containing regimen.
[11]For patients who failed a sofosbuvir-based treatment only.

1.

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^
	Decomp & Post Transplant^					24w^	24w^		
Sovaldi® + peglFN/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; peglFN = peginterferon; w = weeks
†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 peglFN/RBV.
[2]For patients who have failed sofosbuvir + RBV.
[3]For patients who have failed sofosbuvir + RBV +/- peglFN.

[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[1] b				
	Comp		16w[1] b				
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]				
	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[†]	12-16w[p4], 16w[†1]		12w[4]						16w[b]
	Comp	16w[†]	12-16w[p4], 16w[†1]		12w[4]						16w[b]
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
	Comp									12w	12w
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
	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

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.

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**
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[†]	12w[†5], 16w[†5]		12w[5]				
	Comp	16w[†]	12w[†4], 16w[†5]		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^				
	No					12w	12w[1]	24w	

Sovaldi® + RBV	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]				
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]				
	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.

	<table><tr><th>Drug Therapy</th><th>Patient Characteristics</th><th>Authorization Duration</th></tr><tr><td>Sovaldi® + RBV</td><td>Hepatocellular Carcinoma Awaiting Liver Transplantation</td><td>Up to 48 weeks (or until liver transplantation, whichever occurs first)</td></tr></table> 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**.
12/7/2015	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:**

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**
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**
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**
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	**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**. 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**
		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**

	<table><tr><td>**3, 4, 5, or 6**</td><td>Treatment-naïve/ Treatment-experienced</td><td>Sovaldi® + peginterferon alfa + ribavirin</td><td>**12 weeks**</td></tr><tr><td>**3 or 4**</td><td>Treatment-naïve/ Treatment-experienced, peginterferon ineligible</td><td>Sovaldi® + ribavirin</td><td>**24 weeks**</td></tr><tr><td colspan="2">**Hepatocellular Carcinoma Awaiting Liver Transplantation**</td><td>Sovaldi® + ribavirin</td><td>**Up to 48 weeks** **(or until liver transplantation,** **whichever occurs first)**</td></tr></table> 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.