

Generic Name: Simeprevir

Therapeutic Class or Brand Name: Olysio®

Applicable Drugs (if Therapeutic Class): N/A

Date of Origin: 2/10/14 Date Last Reviewed/Revised: 10/31/17

**GPI Code:** <u>1235307710</u>

### Prior Authorization Criteria (may be considered medically necessary when criteria I through VIII are met):

- I. <u>Documented diagnosis of chronic hepatitis C (CHC) genotype 1 or 4 infection.</u>
- II. Documentation that patient meets ONE of the following criteria A, B, or C:
  - A. <u>Has a Metavir score of F3 (advanced fibrosis) or F4 (compensated cirrhosis).</u>
  - B. <u>Is post-liver transplant.</u>
  - C. <u>Has clinically severe extrahepatic manifestations of hepatitis C infection as evidenced by one of the following 1 or 2:</u>
    - 1. Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (i.e. vasculitis).
    - 2. Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis.
- III. Documentation that patient meets ONE of the following criteria A or B:
  - A. Patient has a documented contraindication to Mavyret<sup>TM</sup>, Zepatier<sup>TM</sup>, and Epclusa®.
  - B. Patient is post-liver transplant and criterion 1 is met:
    - 1. Patient has a documented contraindication to Mavyret<sup>TM</sup> and Harvoni® + ribavirin.
- IV. Documentation that patient's hepatitis C drug therapy is prescribed as outlined in the table under Authorization in the Approval Length section.
- V. If the patient has genotype 1a with cirrhosis, then criterion A must also be met:
  - A. <u>Documentation that the patient has tested negative for the NS3 Q80K polymorphism.</u>
- VI. Documentation of patient's Hepatitis C treatment history and baseline viral load.
- VII. Minimum age requirement: 18 years old.
- VIII. Prescriber is a Gastroenterologist, Infectious Disease Specialist, or Hepatologist.

#### **Exclusion Criteria:**

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.



- As retreatment when there has been relapse after, or no response to, a prior treatment course with Daklinza<sup>TM</sup> (daclatasvir), Epclusa® (sofosbuvir/velpatasvir), Harvoni® (ledipasvir/sofosbuvir), Incivek® (telaprevir), Mavyret<sup>TM</sup> (glecaprevir/pibrentasvir), Olysio® (simeprevir), Sovaldi® (sofosbuvir), Technivie<sup>TM</sup> (ombitasvir, paritaprevir, and ritonavir), Victrelis® (boceprevir), Viekira Pak<sup>TM</sup>/XR<sup>TM</sup> (dasabuvir, ombitasvir, paritaprevir, ritonavir), Vosevi® (sofosbuvir/velpatasvir/voxilaprevir), or Zepatier<sup>TM</sup> (elbasvir/grazoprevir).
- Moderate or severe hepatic impairment (Child-Pugh Class B or C).
- Coadministration of Olysio® with any of the drugs listed in the table below:

Drug Class	Drugs within class
Antiarrhythmics	Amiodarone when combined with Sovaldi® (sofosbuvir)
Antibiotics (systemic administration)	Clarithromycin, erythromycin, telithromycin
Anticonvulsants	Carbamazepine, oxcarbazepine, phenobarbital, phenytoin
Antifungals (systemic	Fluconazole, itraconazole, ketoconazole, posaconazole,
administration):	voriconazole
Antimycobacterials	Rifampin, rifabutin, rifapentine
Corticosteroids (systemic)	Dexamethasone
Gastrointestinal Products	Cisapride
Herbal Products	Milk thistle (Silybum marianum), St. John's wort
	(Hypericum perforatum)
HIV Products	Cobicistat-containing product: Any (i.e. Elvitegravir/
	cobicistat/emtricitabine/tenofovir disoproxil fumarate)
	Non-Nucleoside Reverse Transcriptase Inhibitors
	(NNRTIs): Delavirdine, efavirenz, etravirine, nevirapine
	<u>Protease Inhibitors (PIs)</u> : Any (i.e. atazanavir,
	darunavir/ritonavir, fosamprenavir, indinavir, lopinavir,
	nelfinavir, ritonavir, saquinavir, tipranavir)
HMG CO-A Reductase Inhibitors	Atorvastatin > 40 mg per day
	Rosuvastatin > 10 mg per day
Immunosuppressants	Cyclosporine
Other protease inhibitors or NS5A	Daklinza <sup>TM</sup> (daclatasvir), Epclusa®
inhibitors used to treat chronic	(sofosbuvir/velpatasvir), Harvoni® (ledipasvir/
hepatitis C virus infection	sofosbuvir), Mavyret <sup>TM</sup> (glecaprevir/pibrentasvir),
	Technivie <sup>TM</sup> (ombitasvir, paritaprevir, and ritonavir),
	Victrelis® (boceprevir), Viekira Pak <sup>TM</sup> /XR <sup>TM</sup> (dasabuvir,
	ombitasvir, paritaprevir, ritonavir), Vosevi®
	(sofosbuvir/velpatasvir/voxilaprevir), Zepatier <sup>TM</sup>
	(elbasvir/grazoprevir)



### Other Criteria:

• N/A

### **Quantity/Days Supply Restrictions:**

• <u>28 capsules per 28 days.</u>

## **Approval Length:**

• **Authorization:** See table directly below.

Drug Therapy	Cirrhosis	G1a		G1b		G4	
		TN	TE	TN	TE	TN	TE
Olysio® +	No	12w	12w <sup>1</sup>	12w	12w <sup>1</sup>		
Sovaldi <sup>®</sup>	No & Post Transplant <sup>^</sup>	12w^	12w^	12w^	12w^	12w^	12w^
	Comp	24w <sup>n</sup>	24w <sup>n1</sup>	24w	24w <sup>1</sup>		
	Comp & Post Transplant <sup>^</sup>	12w^	12w^	12w^	12w^	12w^	12w^

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

• **Re-Authorization:** N/A

## **Appendix:**

N/A

### **References:**

- 1. <a href="http://hcvguidelines.org/full-report-view.">http://hcvguidelines.org/full-report-view.</a>
- 2. http://www.bcbsnc.com/assets/services/public/pdfs/formulary/olysio\_um\_2015\_criteria.pdf.
- 3. Medi-Span.
- 4. http://www.olysio.com/shared/product/olysio/prescribing-information.pdf.

<sup>&</sup>lt;sup>n</sup>Only for patients who have tested negative for the Q80K variant.

<sup>&</sup>lt;sup>^</sup>For patients who develop HCV infection post-liver transplantation.

<sup>&</sup>lt;sup>1</sup>For patients who have failed pegIFN/RBV.



### Historical Tracking Of Changes Made To Policy

10/31/2017

- 1. **Changed** "Documented diagnosis of chronic hepatitis C (CHC) genotype 1 infection" **to** "Documented diagnosis of chronic hepatitis C (CHC) genotype 1 or 4 infection" **under Prior Authorization Criteria**.
- Changed "III. A. Patient has a documented contraindication to Zepatier<sup>TM</sup> and Epclusa®" to "III.
   Patient has a documented contraindication to Mavyret<sup>TM</sup>, Zepatier<sup>TM</sup>, and Epclusa®" under Prior Authorization Criteria.
- 3. **Changed** "III. B. 1. Patient has a documented contraindication to Harvoni® + ribavirin" **to** "Patient has a documented contraindication to Mavyret<sup>TM</sup> and Harvoni® + ribavirin" **under Prior Authorization Criteria**.
- 4. **Added** "Mavyret<sup>TM</sup> (glecaprevir/pibrentasvir)" **and** "Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)" **to** list of drugs following the statement "As retreatment when there has been relapse after, or no response to, a prior treatment course with…" **under Exclusion Criteria**.
- 5. **Added** "Mavyret<sup>TM</sup> (glecaprevir/pibrentasvir)" **and** "Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)" **under Exclusion Criteria** to table under "Coadministration of Harvoni® with...", line entitled "Other protease inhibitors or NS5A inhibitors used to treat chronic hepatitis C virus infection".
- 6. Changed table below Authorization under Approval Length from (changes made highlighted in yellow):

Drug			Authorization Duration				
Therapy	Cirrhosis	G1a		G1b			
		TN	TE	TN	TE		
Olysio® +	No	12w	$12w^1$	12w	$12w^1$		
Sovaldi®	No & Post Transplant <sup>^</sup>	12w^		12w^			
	Comp	24w <sup>n</sup>	24w <sup>n1</sup>	24w	$24w^1$		
	Comp & Post Transplant <sup>^</sup>	12w^		12w^			

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

RBV = ribavirin; pegIFN = peginterferon; w = weeks

<sup>n</sup>Only for patients who have tested negative for the Q80K variant.

<sup>^</sup>For patients who develop HCV infection post-liver transplantation.

#### to:

<b>Drug Therapy</b>	Cirrhosis	G1a		G1b		G4	
		TN	TE	TN	TE	<mark>TN</mark>	TE
Olysio® +	No	12w	12w <sup>1</sup>	12w	12w <sup>1</sup>		
Sovaldi®	No & Post	12w^	12w <sup>^</sup>	12w^	12w <sup>^</sup>	12w <sup>^</sup>	12w <sup>^</sup>
	Transplant <sup>^</sup>						
	Comp	24w <sup>n</sup>	24w <sup>n1</sup>	24w	24w <sup>1</sup>		
	Comp & Post	12w^	12w <sup>^</sup>	12w^	12w <sup>^</sup>	12w <sup>^</sup>	12w <sup>^</sup>
	Transplant <sup>^</sup>						

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

7/30/2016

1. **Changed** "III. A. Patient has a documented contraindication to Zepatier<sup>TM</sup>" **to** "III. A. Patient has a documented contraindication to Zepatier<sup>TM</sup> and Epclusa®" **under Prior Authorization Criteria**.

<sup>&</sup>lt;sup>1</sup>For patients who have failed pegIFN/RBV.

<sup>&</sup>lt;sup>n</sup>Only for patients who have tested negative for the Q80K variant.

<sup>&</sup>lt;sup>^</sup>For patients who develop HCV infection post-liver transplantation.

<sup>&</sup>lt;sup>1</sup>For patients who have failed pegIFN/RBV.



Historical Tr.										
misiorical fr			of Changes Ma							
	2.	1 i	s met: Patient l	Patient is post-liven as a documented of						d criterion
		Αι	uthorization C	riteria.						
	3.	A	dded "Epclusa@	® (sofosbuvir/velp	atasvir)" <b>und</b>	er Exclusio	on Criter	ia to: 1) List	t of drugs fo	ollowing the
				reatment when the						
	1	wi	with; 2) table under "Coadministration of Olysio® with", line entitled "Other protease inhibitors or							
	1	NS	S5A inhibitors	used to treat chron	ic hepatitis C	virus infec	tion".			
	4.			ra Pak <sup>TM</sup> (ombitasy						
		(da	asabuvir, ombit	asvir, paritaprevir,	, ritonavir)" ii	n list of dru	gs follow	ing the state	ment "As re	etreatment
	1	wł	nen there has be	een relapse after, o	r no response	to, a prior	treatment	course with	" under	Exclusion
			riteria.							
	5.			/grazoprevir)" foll						
	1			ritonavir/dasabuvii						
	1			<b>Exclusion Criter</b>						
	1			otease inhibitors o			o treat ch	ronic hepati	tis C virus i	nfection".
3/21/2016	1.			er" to "patient" th						
	2.			ust be used in com						
				documented contr						
				following criteria						
				ginterferon + ribay						
	1			A or B: A. Patient						
	1			V. Documentation						
	2									
	٥.				table under Authorization in the Approval Length section" <b>under Prior Authorization Cr</b> 3. <b>Changed</b> "As retreatment when there has been relapse after, or no response to, a prior treat					
	1	WI	uu Dakiiliza***	(daciatacume) Hassi	oni® (ladina					
					oni® (ledipas	svir/sofosbu	ıvir), Inci	vek® (telapi	revir), Olys	io®
		(si	meprevir), Sov	aldi® (sofosbuvir)	, Technivie <sup>TM</sup>	svir/sofosbu ¹ (ombitasv	ıvir), Inci ir, paritap	vek® (telapi orevir, and ri	revir), Olys tonavir), V	io® ictrelis®
		(si	meprevir), Sov oceprevir), or V	aldi® (sofosbuvir) <sup>7</sup> iekira Pak™ (omb	, Technivie <sup>TM</sup> pitasvir, parita	svir/sofosbu (ombitasv aprevir, and	ıvir), Inci ir, paritap l ritonavir	vek® (telapi revir, and ri /dasabuvir)"	revir), Olys tonavir), V ' <b>to</b> "As ret	io® ictrelis® reatment
		(si (be wh	meprevir), Sov oceprevir), or V nen there has be	aldi® (sofosbuvir) Viekira Pak™ (ombeen relapse after, o	, Technivie <sup>TM</sup> pitasvir, parita r no response	svir/sofosbu (ombitasvaprevir, and to, a prior	ıvir), Inci ir, paritap I ritonavir treatment	vek® (telapi orevir, and ri /dasabuvir)" course with	revir), Olys tonavir), V ' <b>to</b> "As reta Daklinza <sup>TI</sup>	io® ictrelis® reatment
		(si (be wh (da	meprevir), Sovoceprevir), or Votenthere has be aclatasvir), Har	aldi® (sofosbuvir) <sup>7</sup> iekira Pak <sup>™</sup> (omben relapse after, o voni® (ledipasvir/	, Technivie <sup>TM</sup> pitasvir, parita r no response (sofosbuvir), l	svir/sofosbud (ombitasvaprevir, and to, a prior (ncivek® (t	ivir), Inci ir, paritap ritonavir treatment elaprevir)	vek® (telapi orevir, and ri /dasabuvir)" course with , Olysio® (s	revir), Olys tonavir), V ' <b>to</b> "As reta Daklinza <sup>TI</sup> simeprevir),	io® ictrelis® reatment M , Sovaldi®
		(si (be wh (da (se	meprevir), Sovoceprevir), or Vocenthere has be aclatasvir), Harofosbuvir), Technology	aldi® (sofosbuvir) Viekira Pak <sup>TM</sup> (oml ven relapse after, o voni® (ledipasvir/ hnivie <sup>TM</sup> (ombitasv	o, Technivie <sup>TM</sup> pitasvir, parita r no response (sofosbuvir), l vir, paritaprev	svir/sofosbud (ombitasvaprevir, and to, a prior (ncivek® (to), and rito)	ivir), Inci ir, paritap ritonavir treatment elaprevir) navir), Vi	vek® (telapi orevir, and ri /dasabuvir)" course with , Olysio® (s ctrelis® (boo	revir), Olys tonavir), V ' to "As reta Daklinza <sup>TI</sup> simeprevir), ceprevir), V	io® ictrelis® reatment M , Sovaldi® Viekira
		(si (be wh (da (so Pa	meprevir), Sovoceprevir), or Vocenthere has be aclatasvir), Harofosbuvir), Technology	aldi® (sofosbuvir) Tiekira Pak <sup>TM</sup> (omleen relapse after, ovoni® (ledipasvir/hnivie <sup>TM</sup> (ombitasvr, paritaprevir, and	o, Technivie <sup>TM</sup> pitasvir, parita r no response (sofosbuvir), l vir, paritaprev	svir/sofosbud (ombitasvaprevir, and to, a prior (ncivek® (to), and rito)	ivir), Inci ir, paritap ritonavir treatment elaprevir) navir), Vi	vek® (telapi orevir, and ri /dasabuvir)" course with , Olysio® (s ctrelis® (boo	revir), Olys tonavir), V ' to "As reta Daklinza <sup>TI</sup> simeprevir), ceprevir), V	io® ictrelis® reatment M , Sovaldi® Viekira
	4.	(si (be wh (da (se Pa Ex	meprevir), Sovoceprevir), or Voceprevir), or Voceprevir), Harden (Control of South Part of Control	aldi® (sofosbuvir) Tiekira Pak <sup>TM</sup> (omleen relapse after, ovoni® (ledipasvir/hnivie <sup>TM</sup> (ombitasvr, paritaprevir, and	o, Technivie <sup>TM</sup> pitasvir, parita r no response (sofosbuvir), l vir, paritaprev l ritonavir/das	svir/sofosbu (ombitasv previr, and to, a prior (ncivek® (to vir, and rito (sabuvir), or	nvir), Incirir, paritapil ritonavir treatment elaprevir), Vi Zepatier <sup>T</sup>	vek® (telapi orevir, and ri /dasabuvir)" course with , Olysio® (s ctrelis® (boom (elbasvir/	revir), Olys tonavir), V ' to "As reti Daklinza <sup>T</sup> simeprevir), ceprevir), V grazoprevir	io® ictrelis® reatment  M Sovaldi® Viekira )" under
	4.	(si (be wh (da (se Pa Ex Ac	meprevir), Sovoceprevir), or Voceprevir), or Voceprevir), or Voceprevir), Hardford Voceprevir), Teck <sup>TM</sup> (ombitasvicelusion Criterlided "Zepatier"	aldi® (sofosbuvir) Tiekira Pak <sup>TM</sup> (ombeen relapse after, ovoni® (ledipasvir/hnivie <sup>TM</sup> (ombitasvir, paritaprevir, and ia.	o, Technivie <sup>TM</sup> pitasvir, parita r no response (sofosbuvir), l vir, paritaprev l ritonavir/das ease inhibitor	svir/sofosbud (ombitasvaprevir, and to, a prior (ncivek® (twir, and ritosabuvir), or s or NS5A	nvir), Incirir, paritapi ritonavir treatment elaprevir) navir), Vi Zepatier inhibitors	vek® (telapi orevir, and ri /dasabuvir)" course with , Olysio® (s ctrelis® (boom (elbasvir/	revir), Olys tonavir), V ' to "As reti Daklinza <sup>T</sup> simeprevir), ceprevir), V grazoprevir	io® ictrelis® reatment  M Sovaldi® Viekira )" under
	4.	(si (be) wh (da (so Pa <b>Ex</b> <b>A</b> () viii	meprevir), Sovoceprevir), or Voceprevir), or Voceprevir), or Voceprevir), Harofosbuvir), Teck <sup>TM</sup> (ombitasvicusion Criteralded "Zepatier rus infection" li	aldi® (sofosbuvir) Tiekira Pak <sup>TM</sup> (ombeen relapse after, o voni® (ledipasvir/ hnivie <sup>TM</sup> (ombitasvir, paritaprevir, and Tia.  Tim'' to "Other proto	o, Technivie <sup>TM</sup> pitasvir, parita r no response sofosbuvir), l vir, paritaprev l ritonavir/das ease inhibitor rneath Exclu	svir/sofosbud (ombitasvaprevir, and to, a prior (ncivek® (trir, and ritosabuvir), or s or NS5A sion Criter	nvir), Incirir, paritapil ritonavir treatment elaprevir), Vi Zepatier inhibitorsia.	vek® (telapi previr, and ri /dasabuvir)" course with , Olysio® (s ctrelis® (books) M (elbasvir/s) used to trea	revir), Olys tonavir), V ' to "As reti Daklinza <sup>T</sup> simeprevir), ceprevir), V grazoprevir	io® ictrelis® reatment  M Sovaldi® Viekira )" under
		(si (be) wh (da (so Pa <b>Ex</b> <b>A</b> () viii	meprevir), Sovoceprevir), or Voceprevir), or Voceprevir), or Voceprevir), Harofosbuvir), Teck <sup>TM</sup> (ombitasvicusion Criteralded "Zepatier rus infection" li	aldi® (sofosbuvir) Viekira Pak <sup>TM</sup> (ombeen relapse after, o voni® (ledipasvir/ hnivie <sup>TM</sup> (ombitasvir, paritaprevir, and via.  TM'' to "Other protein on table under collowing Authorization in the collowing in the collowin	pitasvir, paritar no response (sofosbuvir), livir, paritapreval ritonavir/dasease inhibitor reath Excluzation under	svir/sofosbud (ombitasvaprevir, and to, a prior (ncivek® (trir, and ritosabuvir), or s or NS5A sion Criter	nvir), Incirir, paritapil ritonavir treatment elaprevir), Vi Zepatier inhibitorsia.	vek® (telapi previr, and ri /dasabuvir)" course with , Olysio® (s ctrelis® (books) M (elbasvir/s) used to trea	revir), Olys tonavir), V ' to "As reta Daklinza <sup>TY</sup> simeprevir), ceprevir), V grazoprevir	io® ictrelis® reatment  M Sovaldi® Viekira )" under
		(si (be) wh (da (so Pa <b>Ex</b> <b>A</b> () viii	meprevir), Sovoceprevir), or Voceprevir), or Voceprevir), or Voceprevir), Harofosbuvir), Teck <sup>TM</sup> (ombitasvicelusion Criterelded "Zepatier rus infection" linanged table for Treatment Regimen	aldi® (sofosbuvir) Viekira Pak <sup>TM</sup> (ombeen relapse after, o voni® (ledipasvir/ hnivie <sup>TM</sup> (ombitasvir, paritaprevir, and via.  Tim' to "Other proteine on table under	pitasvir, paritar no response (sofosbuvir), livir, paritapreval ritonavir/dasease inhibitor reath Excluzation under	svir/sofosbud (ombitasvaprevir, and to, a prior (ncivek® (trir, and ritosabuvir), or s or NS5A sion Criter	nvir), Incirir, paritapil ritonavir treatment elaprevir), Vi Zepatier inhibitorsia.	vek® (telapineveir, and right in items of the previous and right in items of the previ	revir), Olys tonavir), V ' to "As reta Daklinza <sup>TY</sup> simeprevir), ceprevir), V grazoprevir	io® ictrelis® reatment  M Sovaldi® Viekira )" under
		(si (be) wh (da (so Pa <b>Ex</b> <b>A</b> () viii	meprevir), Sovoceprevir), or Voceprevir), or Voceprevir), or Voceprevir), Hardon Voceprevir), Teck KTM (ombitasvix clusion Criter ded "Zepatier rus infection" linanged table for Treatment Regimen  Olysio® +	aldi® (sofosbuvir)  Ziekira Pak <sup>TM</sup> (ombeen relapse after, ovoni® (ledipasvir/hnivie <sup>TM</sup> (ombitasvir, paritaprevir, and the control of the co	o, Technivie The pitasvir, paritar r no response (sofosbuvir), lavir, paritapreval ritonavir/dastease inhibitor reath Exclusation under story	svir/sofosbud (ombitasvaprevir, and to, a prior (ncivek® (twir, and rito) (abuvir), or sor NS5A sion Criter Approval	nvir), Incirir, paritap I ritonavir treatment elaprevir) navir), Vi Zepatier <sup>T</sup> inhibitors ria. Length fr	vek® (telapionevir, and riporevir, a	revir), Olys tonavir), V ' to "As reta Daklinza <sup>TY</sup> simeprevir), ceprevir), V grazoprevir	io® ictrelis® reatment  M Sovaldi® Viekira )" under
		(si (be) wh (da (so Pa <b>Ex</b> <b>A</b> () viii	meprevir), Sovoceprevir), or Voceprevir), or Voceprevir), or Voceprevir), Harofosbuvir), Teck <sup>TM</sup> (ombitasvicelusion Criterelded "Zepatier rus infection" linanged table for Treatment Regimen	aldi® (sofosbuvir)  Ziekira Pak <sup>TM</sup> (ombeen relapse after, ovoni® (ledipasvir/hnivie <sup>TM</sup> (ombitasvir, paritaprevir, and ria.  The contable under collowing Authorizatreatment Hibrary patients without the contable without the collowing Authorizatreatment without the collowing Authorizatreatment Hibrary patients with the collowing Authorizatreatment Hibrary patients with the collowing Authorizatreatment Hibrary patients w	o, Technivie The pitasvir, paritar r no response (sofosbuvir), lavir, paritapreval ritonavir/dastease inhibitor reath Exclusation under story  we and treatmut cirrhosis	svir/sofosbu 4 (ombitasv aprevir, and to, a prior (ncivek® (tvir, and rito) sabuvir), or s or NS5A sion Criter Approval	nvir), Incirir, paritapil ritonavir treatment elaprevir) navir), Vi Zepatier inhibitorsia.  Length funced	vek® (telapionevir, and ri /dasabuvir)" course with , Olysio® (s ctrelis® (boom M (elbasvir/s used to treat com: Authoriza Duration	revir), Olys tonavir), V ' to "As reta Daklinza <sup>TY</sup> simeprevir), ceprevir), V grazoprevir	io® ictrelis® reatment  M Sovaldi® Viekira )" under
		(si (be) wh (da (so Pa <b>Ex</b> <b>A</b> () viii	meprevir), Sovoceprevir), or Voceprevir), or Voceprevir), or Voceprevir), Hardon Voceprevir), Teck KTM (ombitasvix clusion Criter ded "Zepatier rus infection" linanged table for Treatment Regimen  Olysio® +	aldi® (sofosbuvir) Viekira Pak <sup>TM</sup> (ombeen relapse after, o voni® (ledipasvir/ hnivie <sup>TM</sup> (ombitasvir, paritaprevir, and ria.  The on table under collowing Authoriz  Treatment Hi  Treatment-naïv patients withou Treatment-naïv patients withou	pitasvir, paritar no response (sofosbuvir), livir, paritapreval ritonavir/das ease inhibitor reath Excluzation under story  we and treatmut cirrhosis we and treatm	svir/sofosbu 4 (ombitasv aprevir, and to, a prior (ncivek® (tvir, and rito) sabuvir), or s or NS5A sion Criter Approval	nvir), Incirir, paritapil ritonavir treatment elaprevir) navir), Vi Zepatier inhibitorsia.  Length funced	vek® (telapionevir, and ri /dasabuvir)" course with , Olysio® (sourcelis® (book M (elbasvir/goused to treated com:  Authoriza Duration	revir), Olys tonavir), V ' to "As reta Daklinza <sup>TY</sup> simeprevir), ceprevir), V grazoprevir	io® ictrelis® reatment  M Sovaldi® Viekira )" under
		(si (be) wh (da (so Pa <b>Ex</b> <b>A</b> () viii	meprevir), Sovoceprevir), or Voceprevir), or Voceprevir), or Voceprevir), Hardon Voceprevir), Teck KTM (ombitasvix clusion Criter ded "Zepatier rus infection" linanged table for Treatment Regimen  Olysio® +	aldi® (sofosbuvir)  Ziekira Pak <sup>TM</sup> (ombeen relapse after, ovoni® (ledipasvir/hnivie <sup>TM</sup> (ombitasvir, paritaprevir, and ria.  The contable under collowing Authorizatreatment Hibrary patients without the contable without the collowing Authorizatreatment without the collowing Authorizatreatment Hibrary patients with the collowing Authorizatreatment Hibrary patients with the collowing Authorizatreatment Hibrary patients w	pitasvir, paritar no response (sofosbuvir), livir, paritapreval ritonavir/das ease inhibitor reath Excluzation under story  we and treatmut cirrhosis we and treatm	svir/sofosbu 4 (ombitasv aprevir, and to, a prior (ncivek® (tvir, and rito) sabuvir), or s or NS5A sion Criter Approval	nvir), Incirir, paritapil ritonavir treatment elaprevir) navir), Vi Zepatier inhibitorsia.  Length funced	vek® (telapionevir, and ri /dasabuvir)" course with , Olysio® (s ctrelis® (boom M (elbasvir/s used to treat com: Authoriza Duration	revir), Olys tonavir), V ' to "As reta Daklinza <sup>TY</sup> simeprevir), ceprevir), V grazoprevir	io® ictrelis® reatment  M Sovaldi® Viekira )" under
		(si (bo wh (da (so Pa Acc vin Ch	meprevir), Sovoceprevir), or Voceprevir), or Voceprevir), or Voceprevir), Technological Voceprevir), Voceprevir), Technological Voceprevir), Voceprevir), Technological Voceprevir), Technological Voceprevir), Voceprev	aldi® (sofosbuvir) Viekira Pak <sup>TM</sup> (ombeen relapse after, o voni® (ledipasvir/ hnivie <sup>TM</sup> (ombitasvir, paritaprevir, and ria.  The on table under collowing Authoriz  Treatment Hi  Treatment-naïv patients withou Treatment-naïv patients withou	n, Technivie <sup>TM</sup> pitasvir, parita r no response r sofosbuvir), l vir, paritaprev r ittonavir/das ease inhibitor rneath Exclu zation under story we and treatm at cirrhosis we and treatm irrhosis	svir/sofosbu (ombitasv aprevir, and to, a prior (ncivek® (to) rir, and ritor (sabuvir), or s or NS5A (sion Criter Approval) ent-experie	nvir), Incirir, paritapal ritonavir treatment elaprevir) navir), Vi Zepatier inhibitors ria. Length funced	vek® (telapineveir, and riporevir, a	revir), Olys tonavir), V ' to "As reta Daklinza <sup>TY</sup> simeprevir), ceprevir), V grazoprevir	io® ictrelis® reatment  M Sovaldi® Viekira )" under
		(si (bo wh (da (sc Pa Acc viii Cl	meprevir), Sovoceprevir), or Voceprevir), or Voceprevir), or Voceprevir), Hardon Voceprevir), Teck KTM (ombitasvir), Clusion Criter Ided "Zepatier rus infection" linanged table for Treatment Regimen  Olysio® + Sovaldi®	aldi® (sofosbuvir)  Ziekira Pak <sup>TM</sup> (ombeen relapse after, ovoni® (ledipasvir/hnivie <sup>TM</sup> (ombitasvir, paritaprevir, and ita.  Zimin to "Other protone on table under ollowing Authoriz  Treatment Hi  Treatment-naïv patients withou Treatment-naïv patients with c	o, Technivie The pitasvir, paritar r no response (sofosbuvir), lavir, paritapreval ritonavir/daste ease inhibitor reath Exclusation under story  we and treatment cirrhosis we and treatment restory  Au	svir/sofosbu 4 (ombitasv aprevir, and to, a prior (ncivek® (tvir, and rito) sabuvir), or s or NS5A sion Criter Approval	nvir), Incirir, paritapal ritonavir treatment elaprevir) navir), Vi Zepatier inhibitors ria. Length franced	vek® (telapineveir, and riporevir, a	revir), Olys tonavir), V ' to "As reta Daklinza <sup>TY</sup> simeprevir), ceprevir), V grazoprevir	io® ictrelis® reatment  M Sovaldi® Viekira )" under
		(si (bo wh (da (sc Pa Acc viii Cl	meprevir), Sovoceprevir), or Voceprevir), or Voceprevir), or Voceprevir), Technological Voceprevir), Voceprevir), Technological Voceprevir), Voceprevir), Technological Voceprevir), Technological Voceprevir), Voceprev	aldi® (sofosbuvir) Viekira Pak <sup>TM</sup> (ombeen relapse after, o voni® (ledipasvir/ hnivie <sup>TM</sup> (ombitasvir, paritaprevir, and ria.  The on table under collowing Authoriz  Treatment Hi  Treatment-naïv patients withou Treatment-naïv patients withou	o, Technivie The pitasvir, paritar r no response (sofosbuvir), lavir, paritapreval ritonavir/daste ease inhibitor reath Exclusion under story  we and treatment cirrhosis we and treatment reath irrhosis  Au G1a	svir/sofosbu 4 (ombitasv aprevir, and to, a prior (ncivek® (tvir, and rito) sabuvir), or s or NS5A sion Criter Approval ent-experie	nvir), Incirir, paritapi ritonavir treatment elaprevir) navir), Vi Zepatier inhibitorsia. Length funced	vek® (telapionevir, and riporevir, a	revir), Olys tonavir), V ' to "As reta Daklinza <sup>TY</sup> simeprevir), ceprevir), V grazoprevir	io® ictrelis® reatment  M Sovaldi® Viekira )" under
		(si (bo wh (da (sc Pa Acc viii Cl	meprevir), Sovoceprevir), or Voceprevir), or Voceprevir), or Voceprevir), Hardon Voceprevir), Teck KTM (ombitasvir), Clusion Criter Ided "Zepatier rus infection" linanged table for Treatment Regimen  Olysio® + Sovaldi®	aldi® (sofosbuvir)  Ziekira Pak <sup>TM</sup> (ombeen relapse after, ovoni® (ledipasvir/hnivie <sup>TM</sup> (ombitasvir, paritaprevir, and ita.  Zimin to "Other protone on table under ollowing Authoriz  Treatment Hi  Treatment-naïv patients withou Treatment-naïv patients with c	o, Technivie The pitasvir, paritar r no response (sofosbuvir), lavir, paritapreval ritonavir/daste ease inhibitor reath Exclusation under story  we and treatment cirrhosis we and treatment restory  Au	svir/sofosbu (ombitasv aprevir, and to, a prior (ncivek® (to) rir, and ritor (sabuvir), or s or NS5A (sion Criter Approval) ent-experie	nvir), Incirir, paritapal ritonavir treatment elaprevir) navir), Vi Zepatier inhibitors ria. Length franced	vek® (telapineveir, and riporevir, a	revir), Olys tonavir), V ' to "As reta Daklinza <sup>TY</sup> simeprevir), ceprevir), V grazoprevir	io® ictrelis® reatment  M Sovaldi® Viekira )" under



Historical T	rackino	Of Changes Mo	ide To Policy								
Historical 1	lacking	Olysio® +	No & Post	12w^		12w^					
		Sovaldi®	Transplant <sup>^</sup>								
			Comp	24w <sup>n</sup>	24w <sup>n1</sup>	24w	24w <sup>1</sup>				
			Comp & Post Transplant <sup>^</sup>	12w^		12w^					
		TN = treatmen		ment experie	enced; Co	mp = compe	ensated;	_			
		TN = treatment naïve; TE = treatment experienced; Comp = compensated; RBV = ribavirin; pegIFN = peginterferon; w = weeks									
			ents who have teste			K variant.					
			ho develop HCV		t-liver tra	nsplantation	l <b>.</b>				
			who have failed peg								
			www.hcvguideline	es.org/fullrep	ort" <b>to</b> "h	ttp://hcvgui	delines.org/	full-report-view"			
		under Reference									
			/blue.regence.com/	trgmedpol/d	rugs/dru3	31b.pdf" <b>un</b>	ider Refere	nces because link	is		
		no longer valid.									
12/4/2015			mented diagnosis of								
			ignosis of chronic	hepatitis C (	CHC) gen	otype 1 infe	ection" unde	er Prior Authoriza	ation		
		Criteria.		1		e 1 ·		1			
								be met: A. Membe	r has		
			ntraindication to be						. 1		
		combination with Sovaldi® AND both of criteria A and B must be met: A. Member has a documented contraindication to both Harvoni® AND Viekira Pak <sup>TM</sup> ; B. Member meets one of the following criteria									
								_	eria		
		1 or 2: 1. Member is treatment-naïve; 2. Member has failed prior treatment with peginterferon + ribavirin" under Prior Authorization Criteria.									
	l l					than aritari	ion A must s	also be met: A			
		<b>Added</b> "IV. If the member has genotype 1a with cirrhosis, then criterion A must also be met: A. Documentation that the member has tested negative for the NS3 Q80K polymorphism" <b>under Prior</b>									
		Authorization C		s tested nega	uve for th	.c 1185 Q601	x porymorpi	insin <b>unuci i i io</b> i			
			ocumentation of th	e member's	treatment	history (see	Annendix)	" to "V			
			f member's Hepati								
		Authorization C		ins e treatin		dia susciii	ic virui ioud	under 11101			
				re has been	relanse aft	ter, or no res	sponse to, a	prior treatment cou	ırse		
		5. <b>Changed</b> "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®									
			trelis® (boceprevi								
								to, a prior treatmen	nt		
								(telaprevir), Olys			
	(	(simeprevir), Sov	aldi® (sofosbuvir)	, Technivie <sup>1</sup>	M (ombita	svir, paritap	revir, and ri	itonavir), Victrelis	R		
	(	(boceprevir), or '	Viekira Pak <sup>TM</sup> (oml	bitasvir, pari	taprevir, a	nd ritonavir	/dasabuvir)'	" under Exclusion			
		Criteria.									
	6.	Added "Moderat	e or severe hepatic	impairment	(Child-Pu	ugh Class B	or C)" unde	er Exclusion Crite	eria.		
	7.	Added the follow	ving rows to the t						_		
		Antiarrhythmi						ldi® (sofosbuvir)	]		
		HMG CO-A F	Reductase Inhibitor			0 mg per day					
						0 mg per da					
	8.	Changed the fol	lowing rows on th	e table und	er Exclus	ion Criteria	a from:		_		
		HIV Products						vir/cobicistat/			
						ofovir disop			1		
						Reverse Tra					
				(NNR	(Is): Dela	virdine, efav	virenz, etravi	irine, nevirapine			



Historical Tr	acking Of Changes Made To Policy	
		Protease Inhibitors (PIs): Atazanavir, darunavir/ritonavir, fosamprenavir, lopinavir, indinavir, nelfinavir, ritonavir, saquinavir, tipranavir
	Other protease inhibitors used to	Harvoni® (ledipasvir/sofosbuvir), Victrelis®
	treat chronic hepatitis C virus infection	(boceprevir), Viekira Pak <sup>TM</sup> (ombitasvir, paritaprevir, and ritonavir /dasabuvir)
	to:	monavii /dasabuvii)
	HIV Products	Cobicistat-containing product: Any (i.e. Elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate) Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs): Delavirdine, efavirenz, etravirine, nevirapine Protease Inhibitors (PIs): Any (i.e. atazanavir,
		darunavir/ritonavir, fosamprenavir, lopinavir, indinavir,
	Other mustage inhibitors on NC5A	nelfinavir, ritonavir, saquinavir, tipranavir)  Daklinza <sup>TM</sup> (daclatasvir), Harvoni® (ledipasvir/
	Other protease inhibitors or NS5A inhibitors used to treat chronic hepatitis C virus infection	sofosbuvir), Technivie <sup>TM</sup> (ombitasvir, paritaprevir, and ritonavir), Victrelis® (boceprevir), Viekira Pak <sup>TM</sup>
	O Paragrad "Definitions of Manches To	(ombitasvir, paritaprevir, and ritonavir/dasabuvir)
5/20/2015		eatment History" <b>table from Appendix</b> .  mber meets ONE of the following criteria A through I: A. Has a
4/1/2015	transplant; C. Has clinically severe ex one of the following 1 or 2: 1. Type 2 manifestations (i.e. vasculitis); 2. Prot glomerulonephritis; D. Is coinfected v other coexistent liver disease [i.e. non evidenced by the documentation of sigmeal preparation, household chores, emeets ONE of the following criteria A (compensated cirrhosis); B. Is post-liv of hepatitis C infection as evidenced by cryoglobulinemia with end-organ man membranoproliferative glomeruloneph	vanced fibrosis), or F4 (compensated cirrhosis); B. Is post-liver trahepatic manifestations of hepatitis C infection as evidenced by or 3 essential mixed cryoglobulinemia with end-organ teinuria, nephrotic syndrome, or membranoproliferative with HIV-1; E. Is coinfected with Hepatitis B virus (HBV); F. Has alcoholic steatohepatitis (NASH)]; G. Has debilitating fatigue as gnificant limitations of instrumental activities of daily living (i.e. etc.); H. Has Type 2 diabetes" to "II. Documentation that member A, B, or C: A. Has a Metavir score of F3 (advanced fibrosis) or F4 ver transplant; C. Has clinically severe extrahepatic manifestations by one of the following 1 or 2: 1. Type 2 or 3 essential mixed nifestations (i.e. vasculitis); 2. Proteinuria, nephrotic syndrome, or hritis" under Prior Authorization Criteria.
	Metavir score of F3 (advanced fibrosi Has clinically severe extrahepatic man following 1 or 2: 1. Type 2 or 3 essen vasculitis); 2. Proteinuria, nephrotic si Documentation that member meets Of F2 (fibrosis), F3 (advanced fibrosis), clinically severe extrahepatic manifes following 1 or 2: 1. Type 2 or 3 essen vasculitis); 2. Proteinuria, nephrotic si coinfected with HIV-1; E. Is coinfected disease [i.e. nonalcoholic steatohepati documentation of significant limitatio	s) or F4 (compensated cirrhosis); B. Is post-liver transplant; C. nifestations of hepatitis C infection as evidenced by one of the tial mixed cryoglobulinemia with end-organ manifestations (i.e. yndrome, or membranoproliferative glomerulonephritis" to "II. NE of the following criteria A through I: A. Has a Metavir score of or F4 (compensated cirrhosis); B. Is post-liver transplant; C. Has tations of hepatitis C infection as evidenced by one of the tial mixed cryoglobulinemia with end-organ manifestations (i.e. yndrome, or membranoproliferative glomerulonephritis; D. Is ed with Hepatitis B virus (HBV); F. Has other coexistent liver tis (NASH)]; G. Has debilitating fatigue as evidenced by the ons of instrumental activities of daily living (i.e. meal preparation, 2 diabetes mellitus (insulin resistant); I. Has porphyria cutanea



Historical Tro	ackii	ng Of Changes Made To Policy
2/7/2015	2.	
	3.	Changed "Posaconazole" to "posaconazole" on table for "Coadministration of Olysio® with any of drugs listed in the table below:" under Exclusion Criteria.
	4.	<b>Deleted</b> "Olysio® + peginterferon alfa + ribavirin*" row and corresponding information <b>on table under Approval Length</b> .
1/28/2015	2.	Changed "Documented diagnosis of one of the following conditions A or B AND must meet criteria listed under applicable diagnosis: A. Chronic Genotype 1a Hepatitis C Virus (HCV) infection and criterion 1 is met: 1. Documentation that the member has tested negative for the NS3 Q80K polymorphism; B. Chronic Genotype 1b Hepatitis C Virus (HCV) infection" to "Documented diagnosis of Chronic Genotype 1 Hepatitis C Virus (HCV) infection" under Prior Authorization Criteria.  Changed "Must be used in combination with one of the following regimens A or B AND must meet
		criteria listed under applicable regimen: A. Peginterferon alfa and ribavirin; B. Sovaldi® and criteria 1 and 2 are met: 1. Member is peginterferon ineligible (i.e. the patient is intolerant to or has a contraindication to peginterferon); 2. Member has a documented intolerance to, contraindication to, or does not meet Prior Authorization Criteria for Harvoni®" to "Must be used in combination with one of the following regimens A or B AND must meet criteria listed under applicable regimen: A. Sovaldi® and criterion 1 is met: 1. Member has a documented contraindication to both Harvoni® AND Viekira Pak <sup>TM</sup> ; B. Peginterferon alfa and ribavirin and criteria 1 and 2 are met: 1. Member has a documented contraindication to ALL of the following: Harvoni®, Viekira Pak <sup>TM</sup> , AND Sovaldi®; 2. If the member has genotype 1a, then criterion a must also be met: a. Documentation that the member has tested negative for the NS3 Q80K polymorphism" under Prior Authorization Criteria.
	3.	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 1 or 2: 1. Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (i.e. vasculitis); 2. Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis" under Prior Authorization Criteria.
	4.	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.



		-	
Historical Tra		ng Of Changes Made To Policy	
	5.		sio® with any of drugs listed in the table below:" to
		•	h any of the drugs listed in the table below:" <b>under Exclusion</b>
		Criteria.	
	6.	<b>Added</b> "Other protease inhibitors	used to treat chronic hepatitis C virus infection: Harvoni®
		(ledipasvir/sofosbuvir), Victrelis®	(boceprevir), Viekira Pak <sup>TM</sup> (ombitasvir, paritaprevir, and ritonavir
		/dasabuvir)" on table for "Coadm	ninistration of Olysio® with any of drugs listed in the table
		below:" under Exclusion Criteria	a.
	7.	Moved "Olysio® + peginterferon a	alfa + ribavirin*" <b>row</b> from first listed row to last listed row on table
		under Approval Length.	
	8.	Changed "http://www.hcvguidelin	nes.org/sites/default/files/full_report.pdf" to
		"http://www.hcvguidelines.org/ful	lreport" under References.
	9.	Added "http://www.bcbsnc.com/a	ssets/services/public/pdfs/formulary/olysio_um_2015_criteria.pdf" to
		References.	
11/20/2014	1.	Changed Olysio™ to Olysio®.	
	2.	Changed "Documented diagnosis	of Chronic Genotype 1 Hepatitis C Virus (HCV) infection" and
		"Member must test negative for the	e NS3 Q80K polymorphism" to "Documented diagnosis of one of the
		following conditions A or B AND	must meet criteria listed under applicable diagnosis: A. Chronic
		Genotype 1a Hepatitis C Virus (HC	CV) infection and criterion 1 is met: 1. Documentation that the
		member has tested negative for the	e NS3 Q80K polymorphism; B. Chronic Genotype 1b Hepatitis C
		Virus (HCV) infection" under Pric	or Authorization Criteria section.
	3.	Changed "Must be used in combin	nation with peginterferon alfa and ribavirin" and "Treatment with
		Victrelis® (boceprevir) is contrain	dicated or not recommended" to "Must be used in combination with
		ONE of the following regimens A	or B AND must meet criteria listed under applicable regimen: A.
		Peginterferon alfa and ribavirin; B	. Sovaldi® and criteria 1 and 2 are met: 1. Member is peginterferon
		ineligible (i.e. the patient is intoler	rant to or has a contraindication to peginterferon); 2. Member has a
		documented intolerance to, contrai	indication to, or does not meet Prior Authorization Criteria for
		Harvoni®" under Prior Authoriza	ation Criteria section.
	4.	Changed "There is documentation	n of the member's treatment history (see Appendix)" to
		"Documentation of the member's t	treatment history (see Appendix)" under Prior Authorization
		Criteria.	
	5.		e obtained unless liver biopsy is contraindicated or there is
			rhosis based on imaging studies" to "Documentation that member
		meets ONE of the following criteri	ia A, B, or C: A. Has a Metavir score of F3 (advanced fibrosis) or F4
			t-liver transplant; C. Has serious extrahepatic manifestations of
		hepatitis C infection" under <b>Prior</b>	
	6.		here has been relapse after, or no response to, a prior treatment course
		. 1	® (simeprevir), or Victrelis® (boceprevir)" to "As retreatment when
			response to, a prior treatment course with Harvoni®
			(telaprevir), Olysio® (simeprevir), Sovaldi® (sofosbuvir), or
	_	Victrelis® (boceprevir)" under Ex	
	7.		® with any of drugs listed in the table below:
			Drugs within class
		. •	Clarithromycin, erythromycin, telithromycin
		administration)	
			Carbamazepine, oxcarbazepine, phenobarbital, phenytoin
		<u> </u>	Fluconazole, itraconazole, ketoconazole, Posaconazole,
			voriconazole
		Antimycobacterials I	Rifampin, rifabutin, rifapentine



Historical Tracki	ing Of Changes Made To Policy	
	Corticosteroids (systemic)	Dexamethasone
	Gastrointestinal Products	Cisapride
	Herbal Products	Milk thistle (Silybum marianum), St. John's wort
		(Hypericum perforatum)
	HIV Products	Cobicistat-containing product: Elvitegravir/cobicistat/
		emtricitabine/tenofovir disoproxil fumarate
		Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs):
		Delavirdine, efavirenz, etravirine, nevirapine
		Protease Inhibitors (PIs): Atazanavir, darunavir/ritonavir,
		fosamprenavir, lopinavir, indinavir, nelfinavir, ritonavir,
		saquinavir, tipranavir
	Immunosuppressants	Cyclosporine

<sup>&</sup>quot; to Exclusion Criteria section.

## 9. Changed Approval Length section from:

"Authorization: See table directly below. HCV RNA levels must be obtained at week 4 to determine the Total Authorization Duration.

Re-Authorization: See table directly below. HCV RNA levels must be obtained at week 4 to determine the Total Authorization Duration.

Initial	Continued Authorization	Total Authorization
Authorization	(After initial authorization)	Duration
8 weeks	If HCV RNA $\geq$ 25 IU/mL at week 4:	8 weeks
	No additional authorization	
	(treatment not effective)	
	If HCV RNA < 25 IU/mL at week 4:	12 weeks
	4 additional weeks	

#### to

"Authorization: See table directly below.

Treatment Regimen	Treatment History	Initial Authorization	Continued Authorization (After initial authorization)	Total Authorization Duration for Olysio®
Olysio® +	Treatment-	8 weeks	If HCV RNA $\geq$ 25 IU/mL	8 weeks
peginterferon	naïve		at week 4:	
alfa +	patients,		No additional	
ribavirin*	prior		authorization	
	relapsers,		(treatment not effective)	
	and prior		If HCV RNA < 25 IU/mL	12 weeks
	non-		at week 4:	
	responders		4 additional weeks	
	(including			
	partial and			
	null			
	responders)			

<sup>8.</sup> **Changed** "30 capsules per 30 days" to "28 capsules per 28 days" under **Quantity/Days Supply Restrictions** section.



Historical Tracking C	<u> </u>	To Policy			
	Olysio® +	Treatment-	12 weeks	N/A	12 weeks
	Sovaldi <sup>®</sup>	naïve and			
		treatment-			
		experienced			
		patients			
		without			
		cirrhosis			
		Treatment-	24 weeks	N/A	24 weeks
		naïve and			
		treatment-			
		experienced			
		patients			
		with			
		cirrhosis			
	*HCV RNA leve	ls must be obtained	at week 4 to determine	the Total Authorization Duration	for members treated

<sup>\*</sup>HCV RNA levels must be obtained at week 4 to determine the Total Authorization Duration for members treated with Olysio®, peginterferon alfa, and ribavirin.

Re-Authorization: N/A".

- 10. Added "http://www.hcvguidelines.org/sites/default/files/full\_report.pdf" to References section.
- 11. Changed "http://blue.regence.com/trgmedpol/drugs/dru254.pdf" to

"http://blue.regence.com/trgmedpol/drugs/dru331b.pdf" under **References** section.