

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: 4/26/2018

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</u> 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.
- III. Documentation that patient meets ONE of the following criteria A or B:
 - A. Patient has a documented contraindication to MavyretTM, ZepatierTM, and Epclusa®.
 - B. Patient is post-liver transplant and criterion 1 is met:
 - 1. Patient has a documented contraindication to MavyretTM 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.

judgment in providing the most appropriate care for their patients.

Exclusion Criteria:



- As retreatment when there has been relapse after, or no response to, a prior treatment course with DaklinzaTM (daclatasvir), Epclusa® (sofosbuvir/velpatasvir), Harvoni® (ledipasvir/sofosbuvir), Incivek® (telaprevir), MavyretTM (glecaprevir/pibrentasvir), Olysio® (simeprevir), Sovaldi® (sofosbuvir), TechnivieTM (ombitasvir, paritaprevir, and ritonavir), Victrelis® (boceprevir), Viekira PakTM/XRTM (dasabuvir, ombitasvir, paritaprevir, ritonavir), Vosevi® (sofosbuvir/velpatasvir/voxilaprevir), or ZepatierTM (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 TM (daclatasvir), Epclusa®
inhibitors used to treat chronic	(sofosbuvir/velpatasvir), Harvoni® (ledipasvir/
hepatitis C virus infection	sofosbuvir), Mavyret TM (glecaprevir/pibrentasvir),
	Technivie [™] (ombitasvir, paritaprevir, and ritonavir),
	Victrelis® (boceprevir), Viekira Pak TM /XR TM (dasabuvir,
	ombitasvir, paritaprevir, ritonavir), Vosevi®
	(sofosbuvir/velpatasvir/voxilaprevir), Zepatier TM
	(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	G1a		G1b		G4	
		TN	TE	TN	TE	TN	TE	
Olysio® +	No	12w	12w ¹	12w	12w ¹			
Sovaldi [®]	No & Post Transplant [^]	12w^	12w^	12w^	12w^	12w^	12w^	
	Comp	24w ⁿ	24w ⁿ¹	24w	24w ¹			
	Comp & Post Transplant [^]	12w^	12w^	12w^	12w^	12w^	12w^	

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

• **Re-Authorization:** N/A

Appendix:

N/A

References:

- 1. http://hcvguidelines.org/full-report-view.
- 2. http://www.bcbsnc.com/assets/services/public/pdfs/formulary/olysio_um_2015_criteria.pdf.
- 3. Medi-Span.
- 4. http://www.olysio.com/shared/product/olysio/prescribing-information.pdf.

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

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

¹For patients who have failed pegIFN/RBV.



 diagnosis of chronic hepatitis C (CHC) genotype 1 or 4 infection" under Prior Authorization Cr 2. Changed "III. A. Patient has a documented contraindication to ZepatierTM and Epclusa®" to "III. Patient has a documented contraindication to MavyretTM, ZepatierTM, and Epclusa®" under Prior Authorization Criteria. 3. Changed "III. B. 1. Patient has a documented contraindication to Harvoni® + ribavirin" to "Patie 		No Changes											
2. Changed "III. A Patient has a documented contraindication to Zepatier™ and Epclusa®" to "III. Patient has a documented contraindication to Mavyret™, Zepatier™, and Epclusa®" under Prior Authorization Criteria. 3. Changed "III. B. 1. Patient has a documented contraindication to Harvoni® + ribavirin" to "Patie a documented contraindication to Mavyret™ and Harvoni® + ribavirin" under Prior Authorizat Criteria. 4. Added "Mavyret™ (glecaprevir/pibrentasvir)" and "Vosevi® (sofosbuvir/velpatasvir/voxilaprevi list of drugs following the statement "As retreatment when there has been relapse after, or no resp to, a prior treatment course with" under Exclusion Criteria. 5. Added "Mavyret™ (glecaprevir/pibrentasvir)" and "Vosevi® (sofosbuvir/velpatasvir/voxilaprevi under Exclusion Criteria to table under "Coadministration of Harvoni® with", line entitled "C protease inhibitors or NS5A inhibitors used to treat chronic hepatitis C virus infection". 6. Changed table below Authorization under Approval Length from (changes made highlightey yellow): Drug	2017 1												
Patient has a documented contraindication to Mavyret™, Zepatier™, and Epclusa®" under Prior Authorization Criteria. 3. Changed "III. B. 1. Patient has a documented contraindication to Harvoni® + ribavirin" to "Patie a documented contraindication to Mavyret™ and Harvoni® + ribavirin" under Prior Authorizat Criteria. 4. Added "Mavyret™ (glecaprevir/pibrentasvir)" and "Vosevi® (sofosbuvir/velpatasvir/voxilaprevi list of drugs following the statement "As retreatment when there has been relapse after, or no resp to, a prior treatment course with" under Exclusion Criteria. 5. Added "Mavyret™ (glecaprevir/pibrentasvir)" and "Vosevi® (sofosbuvir/velpatasvir/voxilaprevi list of drugs following the statement "As retreatment when there has been relapse after, or no resp to, a prior treatment course with" under Exclusion Criteria. 5. Added "Mavyret™ (glecaprevir/pibrentasvir)" and "Vosevi® (sofosbuvir/velpatasvir/voxilaprevi list of drugs followir proventase after, or no resp to, a prior treatment course with" under Exclusion Criteria. 6. Changed table below Authorization under Approval Length from (changes made highlighter yellow): Drug	12												
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TN = treatment naïve; TE = treatment experienced; Comp = compensated; RBV = ribavirin; pegIFN = peginterferon; w = weeks "Only for patients who have tested negative for the Q80K variant. "For patients who develop HCV infection post-liver transplantation. "For patients who have failed pegIFN/RBV. to: Drug Therapy Cirrhosis G1a G1b G4				-	24w ⁿ	24w ⁿ¹	24w	24w ¹					
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	icking Of Changes N	Tade To Policy					
	Olysio® +	No	12w	$12w^1$	12w	$12w^1$	
	Sovaldi®	No & Post Transplant [^]	12w^		12w^		
		Comp	24w ⁿ	24w ⁿ¹	24w	24w ¹	
		Comp & Post Transplant [^]	12w^		12w^		
2/4/2015	RBV = ribay "Only for pa For patients For patients Changed "http under Referer Removed "http no longer valid Changed "Doc "Documented of Criteria. Changed "III. a documented of combination w contraindication 1 or 2: 1. Mem ribavirin" under Authorization Authorization Changed "IV. Documentation Authorization Changed "As with Harvoni® (sofosbuvir), V /dasabuvir)" to course with Da (simeprevir), S (boceprevir), o Criteria. Added "Model Added the foll Antiarrhythe HMG CO-A	ent naïve; TE = tre virin; pegIFN = peg tients who have tes who develop HCV who have failed p ://www.hcvguideli tees. b://blue.regence.co. d. cumented diagnosis diagnosis of chroni Must be used in co- contraindication to ith Sovaldi® AND in to both Harvoni@ ber is treatment-na ter Prior Authoriza the member has ge in that the member h Criteria. Documentation of ith of member's Hep Criteria. retreatment when to (ledipasvir/sofosb ictrelis® (bocepre- "As retreatment w klinza TM (daclatase ovaldi® (sofosbuv r Viekira Pak TM (or rate or severe hepa owing rows to the mics Reductase Inhibit ollowing rows on	ginterferon; victed negatives of infection programmers or general programmers of the member at the m	w = weeks for the Q80 oost-liver tran report" to "h I/drugs/dru33 Genotype 1 C (CHC) geno with Sovaldio ni® AND Vi reria A and B dira Pak TM ; B ber has faile ia. ith cirrhosis, gative for the 's treatment ment history n relapse aft k® (telaprev ira Pak TM (o) as been relap i® (ledipasv ie TM (ombita aritaprevir, a ent (Child-Pu rexclusion odarone whe vastatin > 10 ider Exclusi ider Exclusion	K variant. Insplantation Ittp://hevgui 31b.pdf' un Hepatitis Cotype 1 inference B and criterekira Pak ^{TN} must be made and prior treate NS3 Q80 history (see and baseling er, or no reservir), Olysio (mbitasvir, paritagend ritonavir) In Criteria: In combined of mg per date of Criteria: In man production of the production of th	delines.org/ nder Refere Virus (HC ection" under ion A must d" to "III. M et: A. Membrets one of tment with p ion A must K polymorp e Appendix) ne viral load sponse to, a (simeprevioral load reference in load sponse to a (simeprevioral load sponse to a	be met: A. Member fust be used in ber has a documente fee fee following crite peginterferon + also be met: A. hism" under Prior "to "V. I" under Prior prior treatment country, Sovaldi® and ritonavir to, a prior treatment to, a prior treatment of telaprevir), Victrelis® "under Exclusion er Exclusion Crite ldi® (sofosbuvir)



nisioricai Ir	racking Of Changes Made To Policy					
	(NNRTIs): Delavirdine, efavirenz, etravirine, nevirapine 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 (boceprevir), Viekira Pak TM (ombitasvir, paritaprevir, and					
	infection ritonavir /dasabuvir)					
	to:					
	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,					
	nelfinavir, ritonavir, saquinavir, tipranavir)					
	Other protease inhibitors or NS5A Daklinza TM (daclatasvir), Harvoni® (ledipasvir/					
	inhibitors used to treat chronic sofosbuvir), Technivie TM (ombitasvir, paritaprevir, and					
	hepatitis C virus infection ritonavir), Victrelis® (boceprevir), Viekira Pak TM					
	(ombitasvir, paritaprevir, and ritonavir/dasabuvir)					
	9. Removed "Definitions of Member Treatment History" table from Appendix .					
	1. Changed "II. 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 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; 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" to "II. 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 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 .					
4/1/2015	1. Changed "II. 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 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" to "II.					
	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 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; 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,					



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	tarda" under Prior Authorization Criteria.
2/7/2015	1. Reordered "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 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" from IV to II under Prior Authorization Criteria .
	2. Changed "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 TM ; B. Peginterferon alfa and ribavirir and criteria 1 and 2 are met: 1. Member has a documented contraindication to ALL of the following: Harvoni®, Viekira Pak TM , 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" to "Must be used in combination with Sovaldi® and criterion A must be met: A. Member has a documented contraindication to both Harvoni® AND Viekira Pak TM " under Prior Authorization Criteria.
	3. Changed "Posaconazole" to "posaconazole" on table for "Coadministration of Olysio® with any of drugs listed in the table below:" under Exclusion Criteria.
	4. Deleted "Olysio® + peginterferon alfa + ribavirin*" row and corresponding information on table unde Approval Length .
1/28/2015	1. 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 . 2. 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™; 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™, 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 .
	 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. Changed "Coadministered of Olysio® with any of drugs listed in the table below:" to



Historical Tr	ackii	g Of Changes Made To Policy					
		"Coadministration of Olysio® with any of the drugs listed in the table below:" under Exclusion					
		Criteria.					
	6.	Added "Other protease inhibitors used to treat chronic hepatitis C virus infection: Harvoni®					
		(ledipasvir/sofosbuvir), Victrelis® (boceprevir), Viekira Pak TM (ombitasvir, paritaprevir, and ritonavir					
		/dasabuvir)" on table for "Coadministration of Olysio® with any of drugs listed in the table					
		below:" under Exclusion Criteria.					
	7.	loved "Olysio® + peginterferon alfa + ribavirin*" row from first listed row to last listed row on table					
		under Approval Length.					
	8.	Changed "http://www.hcvguidelines.org/sites/default/files/full_report.pdf" to					
		"http://www.hcvguidelines.org/fullreport" under References.					
	9.	Added "http://www.bcbsnc.com/assets/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 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 (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" under Prior Authorization Criteria section.					
	3.	Changed "Must be used in combination with peginterferon alfa and ribavirin" and "Treatment with					
		Victrelis® (boceprevir) is contraindicated 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 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®" under Prior Authorization Criteria section.					
	4.	Changed "There is documentation of the member's treatment history (see Appendix)" to					
		"Documentation of the member's treatment history (see Appendix)" under Prior Authorization					
		Criteria.					
	5.	Changed "Liver biopsy results are obtained unless liver biopsy is contraindicated or there is					
		documentation of compensated cirrhosis based on imaging studies" to "Documentation that member					
		meets ONE of the following criteria A, B, or C: A. Has a Metavir score of F3 (advanced fibrosis) or F4					
		(compensated cirrhosis); B. Is post-liver transplant; C. Has serious extrahepatic manifestations of					
		hepatitis C infection" under Prior Authorization Criteria section.					
	6.	Changed "As retreatment when there has been relapse after, or no response to, a prior treatment course					
		with Incivek® (telaprevir), Olysio® (simeprevir), 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), or					
	_	Victrelis® (boceprevir)" under Exclusion Criteria section.					
	7.	Added "Coadministered of Olysio® with any of drugs listed in the table below:					
		Drug Class Drugs within class					
		Antibiotics (systemic Clarithromycin, erythromycin, telithromycin					
		administration)					
		Anticonvulsants Carbamazepine, oxcarbazepine, phenobarbital, phenytoin					
		Antifungals (systemic Fluconazole, itraconazole, ketoconazole, Posaconazole,					
		administration): voriconazole					
		Antimycobacterials Rifampin, rifabutin, rifapentine					
		Corticosteroids (systemic) Dexamethasone					



Historical Tra	icking (Of Changes Made To Policy		
		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	

Immunosuppressants
" to **Exclusion Criteria** section.

saquinavir, tipranavir

Cyclosporine

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.

<u>Protease Inhibitors (PIs)</u>: Atazanavir, darunavir/ritonavir, fosamprenavir, lopinavir, indinavir, nelfinavir, ritonavir,

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)			
Olysio® +	Treatment-	12 weeks	N/A	12 weeks
Sovaldi [®]	naïve and			

Changed "30 capsules per 30 days" to "28 capsules per 28 days" under Quantity/Days Supply Restrictions section.



Historical Tra	cking Of Changes Mad	le To Policy			
		treatment- experienced patients without			
		cirrhosis Treatment- naïve and treatment- experienced patients with cirrhosis	24 weeks	N/A	24 weeks
	with Olysio [®] , por Re-Authorization:	eginterferon alfa, and N/A". w.hcvguidelines.o	ribavirin. org/sites/default/fi	the Total Authorization Duration of the Total Authorization Duration Duration of the Total Authorization Duration Durati	
	"http://blue.regenc	e.com/trgmedpol	/drugs/dru331b.pd	df' under References section	n.