MEDICATION POLICY

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: 1235307710

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

I. Documented diagnosis of chronic hepatitis C (CHC) genotype 1 or 4 infection.

II. 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 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 Mavyret™, Zepatier™, and Epclusa®.
- B. Patient is post-liver transplant and criterion 1 is met:
  1. Patient has a documented contraindication to Mavyret™ 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. Documentation that the patient has tested negative for the NS3 Q80K polymorphism.

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:

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- As retreatment when there has been relapse after, or no response to, a prior treatment course with Daklinza™ (daclatasvir), Epclusa® (sofosbuvir/velpatasvir), Harvoni® (ledipasvir/sofosbuvir), Incivek® (telaprevir), Mavyret™ (glecaprevir/pibrentasvir), Olysio® (simeprevir), Sovaldi® (sofosbuvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), Victrelis® (boceprevir), Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir), Vosevi® (sofosbuvir/velpatasvir/voxilaprevir), or Zepatier™ (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 administration):	Fluconazole, itraconazole, ketoconazole, posaconazole, 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 Protease Inhibitors (PIs): 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 inhibitors used to treat chronic hepatitis C virus infection	Daklinza™ (daclatasvir), Epclusa® (sofosbuvir/velpatasvir), Harvoni® (ledipasvir/ sofosbuvir), Mavyret™ (glecaprevir/pibrentasvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), Victrelis® (boceprevir), Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir), Vosevi® (sofosbuvir/velpatasvir/voxilaprevir), Zepatier™ (elbasvir/grazoprevir)

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Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- 28 capsules per 28 days.

Approval Length:

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

Drug Therapy	Cirrhosis	G1a		G1b		G4	
		TN	TE	TN	TE	TN	TE
Olysio® + Sovaldi®	No	12w	12w[1]	12w	12w[1]		
	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
[n]Only for patients who have tested negative for the Q80K variant.
^For patients who develop HCV infection post-liver transplantation.
[1]For patients who have failed pegIFN/RBV.

- **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.

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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**.
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** "Patient has a documented contraindication to Mavyret™ and Harvoni® + ribavirin" **under Prior Authorization Criteria**.
4. **Added** "Mavyret™ (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™ (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 Therapy	Cirrhosis	Authorization Duration			
		G1a		G1b	
		TN	TE	TN	TE
Olysio® + Sovaldi®	No	12w	12w[1]	12w	12w[1]
	No & Post Transplant^	12w^		12w^	
	Comp	24w[n]	24w[n1]	24w	24w[1]
	Comp & Post Transplant^	12w^		12w^	

TN = treatment naïve; TE = treatment experienced; Comp = compensated; RBV = ribavirin; pegIFN = peginterferon; w = weeks
[n]Only for patients who have tested negative for the Q80K variant.
^For patients who develop HCV infection post-liver transplantation.
[1]For patients who have failed pegIFN/RBV.

to:

Drug Therapy	Cirrhosis	G1a		G1b		G4	
		TN	TE	TN	TE	TN	TE
Olysio® + Sovaldi®	No	12w	12w[1]	12w	12w[1]		
	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
[n]Only for patients who have tested negative for the Q80K variant.
^For patients who develop HCV infection post-liver transplantation.
[1]For patients who have failed pegIFN/RBV.

7/30/2016

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

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<table>
<tr><td colspan="2">Historical Tracking Of Changes Made To Policy</td></tr>
<tr><td></td><td>2. Changed “III. B. Patient is post-liver transplant” to “III. B. Patient is post-liver transplant and criterion 1 is met: Patient has a documented contraindication to Harvoni® + ribavirin” under Prior Authorization Criteria.
3. Added “Epclusa® (sofosbuvir/velpatasvir)” under Exclusion Criteria to: 1) List of drugs following the statement “As retreatment when there has been relapse after, or no response to, a prior treatment course with…; 2) table under “Coadministration of Olysio® with…”, line entitled “Other protease inhibitors or NS5A inhibitors used to treat chronic hepatitis C virus infection”.
4. Changed “Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir/dasabuvir)” to “Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir)” in list of drugs following the statement “As retreatment when there has been relapse after, or no response to, a prior treatment course with…” under Exclusion Criteria.
5. Added “(elbasvir/grazoprevir)” following Zepatier™ and changed “Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir/dasabuvir)” to “Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir)” under Exclusion Criteria to table under “Coadministration of Olysio® with…”, line entitled “Other protease inhibitors or NS5A inhibitors used to treat chronic hepatitis C virus infection”.</td></tr>
<tr><td>3/21/2016</td><td>1. Changed “member” to “patient” throughout policy.
2. Changed “III. Must be used in 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™; B. Member meets one of the following criteria 1 or 2: 1. Member is treatment-naïve; 2. Member has failed prior treatment with peginterferon + ribavirin” to “III. Documentation that patient meets ONE of the following criteria A or B: A. Patient has a documented contraindication to Zepatier™; B. Patient is post-liver transplant; IV. Documentation that patient's hepatitis C drug therapy is prescribed as outlined in the table under Authorization in the Approval Length section” under Prior Authorization Criteria.
3. Changed “As retreatment when there has been relapse after, or no response to, a prior treatment course with Daklinza™ (daclatasvir), Harvoni® (ledipasvir/sofosbuvir), Incivek® (telaprevir), Olysio® (simeprevir), Sovaldi® (sofosbuvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), Victrelis® (boceprevir), or Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir/dasabuvir)” to “As retreatment when there has been relapse after, or no response to, a prior treatment course with Daklinza™ (daclatasvir), Harvoni® (ledipasvir/sofosbuvir), Incivek® (telaprevir), Olysio® (simeprevir), Sovaldi® (sofosbuvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), Victrelis® (boceprevir), Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir/dasabuvir), or Zepatier™ (elbasvir/grazoprevir)” under Exclusion Criteria.
4. Added “Zepatier™” to “Other protease inhibitors or NS5A inhibitors used to treat chronic hepatitis C virus infection” line on table underneath Exclusion Criteria.
5. Changed table following Authorization under Approval Length from:
<table>
<tr><th>Treatment Regimen</th><th>Treatment History</th><th>Authorization Duration</th></tr>
<tr><td rowspan="2">Olysio® + Sovaldi®</td><td>Treatment-naïve and treatment-experienced patients without cirrhosis</td><td>12 weeks</td></tr>
<tr><td>Treatment-naïve and treatment-experienced patients with cirrhosis</td><td>24 weeks</td></tr>
</table>
to:
<table>
<tr><th rowspan="2">Drug Therapy</th><th rowspan="2">Cirrhosis</th><th colspan="4">Authorization Duration</th></tr>
<tr><th colspan="2">G1a</th><th colspan="2">G1b</th></tr>
<tr><td></td><td></td><td>TN</td><td>TE</td><td>TN</td><td>TE</td></tr>
<tr><td></td><td>No</td><td>12w</td><td>12w[1]</td><td>12w</td><td>12w[1]</td></tr>
</table></td></tr>
</table>

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	Olysio® + Sovaldi®	No & Post Transplant^	12w^		12w^	
		Comp	24w[n]	24w[n1]	24w	24w[1]
		Comp & Post Transplant^	12w^		12w^	

TN = treatment naïve; TE = treatment experienced; Comp = compensated; RBV = ribavirin; pegIFN = peginterferon; w = weeks
[n]Only for patients who have tested negative for the Q80K variant.
^For patients who develop HCV infection post-liver transplantation.
[1]For patients who have failed pegIFN/RBV.

6. **Changed** "http://www.hcvguidelines.org/fullreport" **to** "http://hcvguidelines.org/full-report-view" **under References**.
7. **Removed** "http://blue.regence.com/trgmedpol/drugs/dru331b.pdf" **under References because link is no longer valid**.

12/4/2015

1. **Changed** "Documented diagnosis of Chronic Genotype 1 Hepatitis C Virus (HCV) infection" **to** "Documented diagnosis of chronic hepatitis C (CHC) genotype 1 infection" **under Prior Authorization Criteria**.
2. **Changed** "III. 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™" **to** "III. Must be used in 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™; B. Member meets one of the following criteria 1 or 2: 1. Member is treatment-naïve; 2. Member has failed prior treatment with peginterferon + ribavirin" **under Prior Authorization Criteria**.
3. **Added** "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" **under Prior Authorization Criteria**.
4. **Changed** "IV. Documentation of the member's treatment history (see Appendix)" **to** "V. Documentation of member's Hepatitis C treatment history and baseline viral load" **under Prior Authorization Criteria**.
5. **Changed** "As retreatment when there has been relapse after, or no response to, a prior treatment course with Harvoni® (ledipasvir/sofosbuvir), Incivek® (telaprevir), Olysio® (simeprevir), Sovaldi® (sofosbuvir), Victrelis® (boceprevir), or Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir /dasabuvir)" **to** "As retreatment when there has been relapse after, or no response to, a prior treatment course with Daklinza™ (daclatasvir), Harvoni® (ledipasvir/sofosbuvir), Incivek® (telaprevir), Olysio® (simeprevir), Sovaldi® (sofosbuvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), Victrelis® (boceprevir), or Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir/dasabuvir)" **under Exclusion Criteria**.
6. **Added** "Moderate or severe hepatic impairment (Child-Pugh Class B or C)" **under Exclusion Criteria**.
7. **Added the following rows to the table under Exclusion Criteria:**

Antiarrhythmics	Amiodarone when combined with Sovaldi® (sofosbuvir)
HMG CO-A Reductase Inhibitors	Atorvastatin > 40 mg per day Rosuvastatin > 10 mg per day

8. **Changed the following rows on the table under Exclusion Criteria from:**

HIV Products	Cobicistat-containing product: Elvitegravir/cobicistat/ emtricitabine/tenofovir disoproxil fumarate Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs): Delavirdine, efavirenz, etravirine, nevirapine

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	Protease Inhibitors (PIs): Atazanavir, darunavir/ritonavir, fosamprenavir, lopinavir, indinavir, nelfinavir, ritonavir, saquinavir, tipranavir
Other protease inhibitors used to treat chronic hepatitis C virus infection	Harvoni® (ledipasvir/sofosbuvir), Victrelis® (boceprevir), Viekira Pak™ (ombitasvir, paritaprevir, and 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 inhibitors used to treat chronic hepatitis C virus infection	Daklinza™ (daclatasvir), Harvoni® (ledipasvir/ sofosbuvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), Victrelis® (boceprevir), Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir/dasabuvir)

9. **Removed** "Definitions of Member Treatment History" **table from Appendix**.

5/20/2015	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, household chores, etc.); H. Has Type 2 diabetes mellitus (insulin resistant); I. Has porphyria cutanea tarda" **under Prior Authorization Criteria**.

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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™; 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" **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™" **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 under 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**. 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**.

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<table>
<tr><td colspan="2">Historical Tracking Of Changes Made To Policy</td></tr>
<tr><td></td><td>5. Changed “Coadministered of Olysio® with any of drugs listed in the table below:” to “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™ (ombitasvir, paritaprevir, and ritonavir /dasabuvir)” on table for “Coadministration of Olysio® with any of drugs listed in the table below:” under Exclusion Criteria.
7. Moved “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.</td></tr>
<tr><td>11/20/2014</td><td>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:
<table>
<tr><th>Drug Class</th><th>Drugs within class</th></tr>
<tr><td>Antibiotics (systemic administration)</td><td>Clarithromycin, erythromycin, telithromycin</td></tr>
<tr><td>Anticonvulsants</td><td>Carbamazepine, oxcarbazepine, phenobarbital, phenytoin</td></tr>
<tr><td>Antifungals (systemic administration):</td><td>Fluconazole, itraconazole, ketoconazole, Posaconazole, voriconazole</td></tr>
<tr><td>Antimycobacterials</td><td>Rifampin, rifabutin, rifapentine</td></tr>
</table></td></tr>
</table>

Historical Tracking 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

" to **Exclusion Criteria** section.

8. **Changed** "30 capsules per 30 days" to "28 capsules per 28 days" under **Quantity/Days Supply Restrictions** 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 Authorization	**Continued Authorization** (After initial authorization)	**Total Authorization Duration**
8 weeks	If HCV RNA ≥ 25 IU/mL at week 4: **No additional authorization** (treatment not effective)	**8 weeks**
	If HCV RNA < 25 IU/mL at week 4: **4 additional weeks**	**12 weeks**

"

to:

"Authorization: See table directly below.

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

Historical Tracking Of Changes Made To Policy

	Olysio® + Sovaldi®	Treatment-naïve and treatment-experienced patients without cirrhosis	**12 weeks**	**N/A**	**12 weeks**
		Treatment-naïve and treatment-experienced patients with cirrhosis	**24 weeks**	**N/A**	**24 weeks**

*****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. C**hanged** "http://blue.regence.com/trgmedpol/drugs/dru254.pdf" to "http://blue.regence.com/trgmedpol/drugs/dru331b.pdf" under **References** section.