



STATE OF WEST VIRGINIA  
DEPARTMENT OF HEALTH AND HUMAN RESOURCES  
BUREAU FOR MEDICAL SERVICES



## Office of Pharmacy Services Prior Authorization Criteria

**OLYSIO<sup>®</sup> (Simeprevir)**  
***Effective 1/28/2016***

[Prior Authorization Request Form](#)  
[Prior Authorization Continuation Request Form](#)  
[Patient Consent Form](#)  
[Preferred HepC Regimens \(Attachment A\)](#)

### Criteria for Approval

1. All requests for Olysio must clearly indicate why the patient cannot take a preferred medication indicated for their HCV genotype (See [Attachment A](#) for a list of preferred regimens per genotype); **AND**
2. All documentation must be fully completed, including the patient consent form. A fibrosis score substantiated by a validated evidence-based method must be reported when requesting prior authorization; **AND**
3. Patient must have a documented **fibrosis level  $\geq$  F3**; **AND**
4. Patient must be diagnosed chronic Hepatitis C Genotype 1; **AND**
5. Olysio must be prescribed by, or in conjunction with, a board certified gastroenterologist, hepatologist or infectious disease physician; **AND**
6. Patient must be eighteen (18) years of age or older; **AND**
7. Patient may not be pregnant, as verified by a negative pregnancy test. In addition, the patient must attest that two forms of birth control will be used to prevent pregnancy during the treatment as indicated by the patient's signature on the Patient Consent Form; **AND**
8. Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months, as indicated by their signature on the Patient Consent form; **AND**
9. Patient must agree to complete the full regimen and the patient and the provider must agree that an SVR12 and SVR24 will be collected and submitted to WV Medicaid to verify therapy success; **AND**
10. If used in a regimen NOT containing Sovaldi, then the patient must not be infected with HCV genotype 1a containing the Q80K polymorphism; **AND**

### Duration of Approval

1. Initial approval is for six (6) weeks. All indications require submission of an HCV RNA level at the start of therapy and at treatment week 4 (TW4).



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2. Continued coverage after week 6 depends upon receipt of an HCV RNA level at treatment week 4 (TW4), documentation of patient compliance, continued abstinence and an HCV RNA < 25 IU/ml. **Failure to obtain and report a treatment week 4 HCV RNA load will result in denial of further coverage.**
3. After discontinuation of simeprevir at week 12, it is expected that an HCV RNA at TW 12 will also be collected to evaluate continuation of ribavirin and peginterferon.

Table 1 – Covered Regimens		
Documented HCV Genotype / Fibrosis Stage		
Diagnosis	Approved Treatment Regimen	Regimen Duration
<b>HCV genotype 1</b>		
<ul style="list-style-type: none"> <li>• Treatment naïve patients infected with HCV with or without compensated cirrhosis</li> </ul>	<i>Triple Therapy</i> simeprevir + peginterferon alfa + ribavirin*	12 weeks of simeprevir with an additional 12 weeks of interferon + ribavirin
	<i>Dual Therapy (interferon-ineligible)</i> sofosbuvir + simeprevir	12 weeks

**Diagnostic/Disease Severity Evidence (must be attached to request)**

1. Cirrhosis may be substantiated either through biopsy or the presence of **at least two** of the following clinical features:
  - a. Cirrhotic features on imaging
  - b. Ascites
  - c. Esophageal varices
  - d. Reversed AST:ALT ratio (> 1), thrombocytopenia (< 130,000 platelets/μL), and coagulopathy (INR > 2)

**Criteria for Denial**

1. Patient is pregnant.
2. Requests submitted with incomplete documentation will be denied.
3. Failure to report a fibrosis score.
4. Patient has decompensated cirrhosis (defined as a Child-Pugh score greater than 6 [class B or C]).
5. Evidence exists that the patient has abused any illicit substance or alcohol in the past three (3) months.



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6. Patient has severe renal impairment (eGFR < 30 mL/min/1.73m<sup>2</sup>) or end stage renal disease (ESRD) requiring hemodialysis.
7. Patient has previously failed hepatitis protease inhibitor therapy (e.g. telaprevir (Incivek), boceprevir (Victrelis), simeprevir (Olysio)).
8. Patient is taking any concomitant medication that has a significant clinical interaction with simeprevir (as indicated in the manufacturer's package insert).
9. Patient refuses treatment with Interferon but does not meet definition of Interferon Ineligibility. **Interferon Alfa Ineligible** is defined as:
  - a. Intolerance to interferon alfa – patient must have documented trial
  - b. Autoimmune hepatitis and other autoimmune disorders
  - c. Hypersensitivity to peginterferon alfa or any of its components
  - d. Decompensated hepatic disease
  - e. A baseline neutrophil count below 1,500/ $\mu$ L, a baseline platelet count below 90,000/ $\mu$ L or baseline hemoglobin below 10 g/dL

### **Additional Considerations**

1. It is highly recommended that the patient vaccinated against Hepatitis A and Hepatitis B.
2. Simeprevir combination treatment with ribavirin or peginterferon alfa/ribavirin is contraindicated in women who are pregnant or may become pregnant and men whose female partners are pregnant because of the risks for birth defects and fetal death associated with ribavirin.
3. Simeprevir is an HCV NS3/4A protease inhibitor.
4. Coverage shall be for one successful course of therapy in a lifetime. Success of therapy shall be judged by undetectable SVR12 and SVR24 HCV RNA levels. If RNA levels have not been submitted, then it will be assumed that therapy was successful. Re-infection will not be covered. Exceptions may be allowed on a case-by-case basis.
5. **For HCV/HIV co-infections all requests must be reviewed for drug-drug interactions prior to approval. Please submit a list of the patient's current HIV regimen along with your request for coverage of Olysio.**
6. Lost or stolen medication replacement request will not be authorized.

### **References**

- 1) Olysio [package insert]. Janssen Therapeutics; Titusville, NJ. April 2015.
- 2) Sovaldi [package insert]. Foster City, CA; Gilead, August 2015.
- 3) American Association for the Study of Liver Diseases Infectious Diseases Society of America: Recommendations for testing, managing and treating hepatitis C. Available at: <http://www.hcvguidelines.org/>. Accessed 11/23/2015.
- 4) The alcohol use disorders identification test. AUDIT C test. Available at: <http://www.hepatitis.va.gov/provider/tools/audit-c.asp> Accessed April 25, 2014.



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- 5) Brief counseling for alcohol misuse. Available at: <http://www.hepatitis.va.gov/products/video-alcohol-brief-counseling.asp>. Accessed April 25, 2014.
- 6) Helping patients who drink too much. A clinician's guide. US Department of Health and Human Services. National Institute of Alcohol Abuse and Alcoholism. 2005. Available at: [http://pubs.niaaa.nih.gov/publications/Practitioner/CliniciansGuide2005/clinicians\\_guide.htm](http://pubs.niaaa.nih.gov/publications/Practitioner/CliniciansGuide2005/clinicians_guide.htm). Accessed April 25, 2014.
- 7) Clinician's screening tool for drug use in general medical settings. NIDA drug screening tool. National Institutes of Health National Institute on Drug Abuse. Available at: <http://www.drugabuse.gov/nmassist/>. Accessed April 25, 2014.
- 8) Theise ND. Liver biopsy assessment in chronic viral hepatitis: a personal, practical approach. *Modern Pathology*. 2007; 20: S3–S14.
- 9) European Association of the Study of the Liver. EASL recommendations on treatment of hepatitis C 2014. April 2014. Available at: <http://files.easl.eu/easl-recommendations-on-treatment-of-hepatitis-C/index.html>. Accessed April 23, 2014.
- 10) World Health Organization. Guidelines for the screening, care and treatment of persons with hepatitis C infection. April 2014. Available at: [http://apps.who.int/iris/bitstream/10665/111747/1/9789241548755\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/111747/1/9789241548755_eng.pdf?ua=1). Accessed April 23, 2014.
- 11) Shiffman ML, Benhanou Y. HCV F1/F2 patients: treat now or continue to wait. *Liver International*. 2014; ISSN 1478-3223. 79-84. doi:10.1111/liv.12408.
- 12) Chronic Hepatitis C virus (HCV) infection: treatment considerations from the Department of Veterans Affairs National Hepatitis C Resource Center Program and the Office of Public Health. March 27, 2014; data last reviewed on March 6, 2014.