



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



Office of Pharmacy Service
Prior Authorization Criteria

Olysio[®] (Simeprevir) for Hepatitis C (HCV)
[Prior Authorization Request Form](#)
[Prior Authorization Continuation Request Form](#)

Criteria for Approval

1. Patient must be diagnosed Hepatitis C Genotype 1; **AND**
2. Olysio must be prescribed by, or in conjunction with, a board certified gastroenterologist, hepatologist or infectious disease physician; **AND**
3. Patient must have a documented diagnosis of **compensated cirrhosis** or a **fibrosis level of F3 or greater** (see Table 1 below); **AND**
4. Patient must be eighteen (18) years of age or older; **AND**
5. Patient must be vaccinated against Hepatitis A and Hepatitis B; **AND**
6. 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**
7. Patient CANNOT have failed therapy with an oral protease inhibitor indicated for HCV (e.g., Incivek, Victrelis, or Olysio); **AND**
8. Patient has abstained from the use of illicit drugs and alcohol for a minimum of six (6) months, as indicated by the patient's 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. Olysio will only be authorized as part of a combination regimen. (See Table 1 for covered regimens); **AND**
11. If used in a regimen NOT containing Sovaldi, then the patient must not be infected with HCV genotype 1a containing the Q80K polymorphism; **AND**
12. Olysio will **not** be authorized if the patient is co-infected with HIV.

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).
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.



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Table 1 – Covered Regimens		
Documented HCV Genotype / Fibrosis Stage		
Diagnosis	Approved Treatment Regimen	Regimen Duration
<i>HCV genotype 1 / ≥ Stage F3 (cirrhosis or bridging fibrosis)</i>		
<ul style="list-style-type: none"> • Treatment naïve patients infected with HCV with or without compensated cirrhosis 	<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)
2. Fibrosis levels must be substantiated via biopsy or other accepted method (e.g. FibroSure Assay)

Criteria for Denial

1. Patient is pregnant.
2. Prescriber has determined that the patient has not abstained from the use of illicit drugs and/or alcohol for at least six (6) months prior to the start of treatment.
3. Diagnosis for any genotype other than GT 1.
4. Patient has previously failed hepatitis protease inhibitor therapy (e.g. telaprevir (Incivek), boceprevir (Victrelis), simeprevir (Olysio)).
5. Patient has decompensated cirrhosis (defined as a Child-Pugh score greater than 6 [class B or C]).
6. Patient is post-liver transplant (safety and efficacy have not been established).
7. Patient has severe renal impairment (eGFR < 30 mL/min/1.73m²) or end stage renal disease (ESRD) requiring hemodialysis.
8. Patient is taking any concomitant medication that has a significant clinical interaction with simeprevir (as indicated in the manufacturer’s package insert).



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9. Patient refuses treatment with Interferon but does not meet definition of Interferon Ineligibility. **Interferon Alfa Ineligible** is defined as:
- Intolerance to interferon alfa – patient must have documented trial
 - Autoimmune hepatitis and other autoimmune disorders
 - Hypersensitivity to peginterferon alfa or any of its components
 - Decompensated hepatic disease
 - A baseline neutrophil count below 1,500/ μ L, a baseline platelet count below 90,000/ μ L or baseline hemoglobin below 10 g/dL

Additional Considerations

- 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.
- Simeprevir is an HCV NS3/4A protease inhibitor.
- 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.
- Lost or stolen medication replacement request will not be authorized.

References

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- Brief counseling for alcohol misuse. Available at: <http://www.hepatitis.va.gov/products/video-alcohol-brief-counseling.asp>. Accessed April 25, 2014.
- 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. Accessed April 25, 2014.
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- Theise ND. Liver biopsy assessment in chronic viral hepatitis: a personal, practical approach. *Modern Pathology*. 2007; 20: S3–S14.



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- 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. 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.

Reviewed and Approved
Drug Utilization Review Board
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