

## **Olysio™ (Simeprevir) for Hepatitis C (HCV)**

### **Criteria for Approval - Initial**

1. HCV genotype 1 **NOT** containing the NS3 Q80K polymorphism if type 1a; **AND**
2. Adult patient age  $\geq$  18 years old; **AND**
3. Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months as evidenced by negative urine confirmation tests in each of the two months immediately prior to therapy (results must be submitted with request); **AND**
4. HCV protease inhibitor naïve (i.e. no previous therapy with an oral protease inhibitor indicated for HCV (e.g., telaprevir (Incivek®), boceprevir (Victrelis®), or simeprevir (Olysio™)); **AND**
5. Agrees to concurrent therapy with ribavirin and peginterferon; **AND**
6. Not post-liver transplant; **AND**
7. Not HCV/HIV co-infected; **AND**
8. Has Fibrosis Stage  $\geq$  F3 (bridging fibrosis or cirrhosis); **AND**
9. Not receiving concomitant therapy with sofosbuvir (Sovaldi™).

### **Criteria for Approval – Renewal (at Treatment Week 8)**

1. HCV genotype 1 **NOT** containing the NS3 Q80K polymorphism if type 1a; **AND**
2. Adult patient age  $\geq$  18 years old; **AND**
3. Patient is abstaining from the use of illicit drugs and alcohol as evidenced by urine confirmation tests (results must be submitted with renewal request); **AND**
4. Agrees to continued concurrent therapy with ribavirin and peginterferon; **AND**
5. Not post-liver transplant; **AND**
6. Not HCV/HIV co-infected; **AND**
7. Not receiving concomitant therapy with another hepatitis C direct acting agent (i.e., telaprevir (Incivek®), boceprevir (Victrelis®), or sofosbuvir (Sovaldi™)); **AND**
8. Patient has been compliant with previous weeks of treatment during the treatment course; **AND**
9. HCV-RNA  $<$  25 IU/mL at treatment week 4.  
*Note: If HCV-RNA  $>$  25 IU/mL at Week 4, treatment continuation will not be approved.*

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**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/ $\mu$ L), and coagulopathy (INR > 2)
2. Bridging fibrosis must be substantiated via biopsy.

**Duration of Approval**

1. Initial
  - 8 weeks
2. Renewal
  - 4 weeks (for a total of 12 weeks of therapy); HCV-RNA must be less than 25 IU/mL at week 4
3. Limit
  - One course of therapy, not to exceed 8 weeks for non-responders or 12 weeks for responders as evidenced by HCV-RNA < 25 IU/mL at week 4
4. Lost or stolen medication
  - Lost or stolen medication replacement requests will not be authorized.

**Quantity Limit**

One 150 mg tablet per day (28 tablets/28 days)

**Criteria for Denial**

1. Patient is pregnant or lactating.
2. Patient is not abstaining from the use of illicit drugs and alcohol for at least three (3) months as evidenced by submitted urine confirmation test results.
3. Patient is not simeprevir naïve. Patients who have had an interruption in simeprevir therapy or who have failed simeprevir therapy previously are not candidates.
4. Patient receiving a concomitant hepatitis C direct acting agent (i.e., telaprevir (Incivek<sup>®</sup>), boceprevir (Victrelis<sup>®</sup>), or sofosbuvir (Sovaldi<sup>™</sup>)).
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 is taking a concomitant medication that has a significant clinical interaction with simeprevir:
  - Moderate or strong inducers (e.g., carbamazepine, phenobarbital, phenytoin, etc.) or inhibitors (e.g., ritonavir, ketoconazole, clarithromycin, etc.) of cytochrome P450 3A (CYP3A)

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**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 a NS3/4A protease inhibitor.

**References**

1. Olysio [package insert]. Janssen Therapeutics; Titusville, NJ. November 2013.
2. 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 February 18, 2014.
3. Poynard T, Ratziu V, Benmanov Y, DiMartino V, Bedossa P, Opolon P. Fibrosis in patients with hepatitis c: detection and significance. *Semin Liver Dis.* 2000;20(1). Retrieved from [www.medscape.com](http://www.medscape.com). Accessed February 26, 2014.