Prior Authorization Guideline

Guideline Name Olysio (simeprevir)

Formulary UnitedHealthcare Community & State

Formulary Note

Approval Date 2/19/2014

Revision Date 7/9/2014

1 . Indications

Drug Name: Olysio (simeprevir)

Indications

Chronic Hepatitis C (CHC)
Is indicated for the treatment of CHC infection as a component of a combination antiviral treatment regimen. Olysio efficacy has been established in combination with peginterferon alfa and ribavirin, in HCV genotype 1 infected subjects with compensated liver disease (including cirrhosis). The following points should be considered when initiating OLYSIO for treatment of chronic hepatitis C infection: - Olysio must not be used as monotherapy. - Olysio efficacy in combination with peginterferon alfa and ribavirin is influenced by baseline host and viral factors. - Olysio efficacy in combination with peginterferon alfa and ribavirin is substantially reduced in patients infected with HCV genotype 1a with an NS3 Q80K polymorphism at baseline compared to patients infected with hepatitis C virus (HCV) genotype 1a without the Q80K polymorphism. Screening patients with HCV genotype 1a infection for the presence of virus with the NS3 Q80K polymorphism at baseline is strongly recommended. Alternative therapy should be considered for patients infected with HCV genotype 1a containing the Q80K polymorphism. - Olysio efficacy has not been studied in patients who have previously failed therapy with a treatment regimen

that includes Olysio or other HCV protease inhibitors.

2 . Criteria

Product Name: Olysio (simeprevir)

Diagnosis	Chronic Hepatitis C - Genotype 1 - Peginterferon Eligible – Olysio + Alfa Interferons + Ribavirin Treatment Regimen
Approval Length	12 Week
Guideline Type	Prior Authorization

Approval Criteria

1 Submission of medical records (e.g., chart notes, laboratory values) documenting one of the following:

1.1 Both of the following:

1.1.1 Diagnosis of chronic hepatitis C genotype 1a infection [1]

AND

1.1.2 One of the following:

1.1.2.1 Patient does not have the NS3 Q80K polymorphism [1]

OR

1.1.2.2 Patient has IL28B-CC genotype status [2]

OR

1.2 Diagnosis of chronic hepatitis C genotype 1b infection [1]

AND

2 One of the following:

2.1 Evidence of stage 3 or stage 4 hepatic fibrosis, including one of the following:

- Liver biopsy confirming a METAVIR score of F3 or F4, or alternative scoring equivalent*
- Transient elastography (Fibroscan) score greater than or equal to 9.5 kPa
- FibroTest (FibroSURE) score of greater than or equal to 0.58
- APRI score greater than 1.5
- Radiological imaging consistent with cirrhosis (eg, evidence of portal hypertension)
- Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician

OR

2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting that patient has serious extrahepatic manifestations of HCV infection (i.e., leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia) [7]

AND

3 Patient has not experienced failure with a previous treatment regimen that includes Olysio or other HCV NS3/4A protease inhibitors [e.g., Incivek (telaprevir), Victrelis (boceprevir)] [1]

AND

4 Submission of medical records (e.g., chart notes, laboratory values) documenting that patient is without decompensated liver disease (defined as Child-Pugh Class B or C) [1]

AND

5 Used in combination with peginterferon alfa and ribavirin [1]

AND

6 Prescribed by one of the following: [2]

- Hepatologist
- Gastroenterologist
- Infectious disease specialist

AND

7 One of the following:

7.1 Patient has no known history of illicit drug abuse or alcohol abuse

OR

7.2 For a patient with a known prior history of illicit drug abuse or alcohol abuse:

7.2.1 Patient has abstained from the use of illicit drugs and alcohol abuse for the past 6 months

AND

7.2.2 For a patient with a prior history of illicit drug abuse, submission of a negative urine drug screen collected within 30 days prior to onset of treatment

Notes	*Refer to Background Section for alternative scoring equivalents

Product Name: Olysio (simeprevir)

Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 1 - Peginterferon Ineligible – Olysio + Sovaldi Treatment Regimen (Off-Label)
Approval Length	12 Week
Guideline Type	Prior Authorization

Approval Criteria

1 One of the following:

1.1 All of the following:

1.1.1 Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C genotype 1

AND

1.1.2 One of the following:

1.1.2.1 Submission of medical records (e.g., chart notes, laboratory values) documenting evidence of stage 3 or stage 4 hepatic fibrosis including one of the following: [3, A]

- Liver biopsy confirming a METAVIR score of F3 or F4, or alternative scoring equivalent*
- Transient elastography (Fibroscan) score greater than or equal to 9.5 kPa
- FibroTest (FibroSURE) score of greater than or equal to 0.58
- APRI score greater than 1.5
- Radiological imaging consistent with cirrhosis (eg, evidence of portal hypertension)
- Physical findings or clinical evidence consistent with cirrhosis as attested by the prescribing physician

OR

1.1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting that patient has serious extrahepatic manifestations of HCV infection (i.e., leukocytoclastic vasculitis, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia) [7]

OR

1.1.2.3 Patient is co-infected with HIV [3]

AND

1.1.3 Submission of medical records (e.g., chart notes, laboratory values) documenting that patient is ineligible for treatment with peginterferon alfa, defined by at least one of the following: [2, 3, 5]

- Autoimmune hepatitis or autoimmune disorders (eg, dermatomyositis, immune

[idiopathic)] thrombocytopenic purpura, inflammatory bowel disease, interstitial lung disease, interstitial nephritis, polymyositis, psoriasis, rheumatoid arthritis, sarcoidosis, and systemic lupus erythematosus)
- Major uncontrolled depressive illness
- History of psychosis, schizophrenia, bipolar disorder, schizoaffective disorder, or suicidal ideation
- Uncontrolled seizures
- Moderate or severe retinopathy
- Poorly controlled diabetes
- Baseline neutrophil count below 1,500/ ?L
- Baseline platelet count below 70,000/ ?L
- Baseline hemoglobin below 10 g/dL
- Significant ischemic cardiac disease
- Prior intolerance or hypersensitivity (urticaria, angioedema, bronchoconstriction, anaphylaxis, or Stevens-Johnson syndrome) to interferon therapy

OR

1.2 Submission of medical records (e.g., chart notes, laboratory values) documenting genotype 1 HCV reinfection following liver transplantation [3]

AND

2 Used in combination with Sovaldi (sofosbuvir) [6, C]

AND

3 Prescribed by one of the following: [2]

- Hepatologist
- Gastroenterologist
- Infectious disease specialist

AND

4 One of the following:

4.1 Patient has no known history of illicit drug abuse or alcohol abuse

OR

4.2 For a patient with a known prior history of illicit drug abuse or alcohol abuse:

4.2.1 Patient has abstained from the use of illicit drugs and alcohol abuse for the past 6 months

AND

4.2.2 For a patient with a prior history of illicit drug abuse, submission of a negative urine drug screen collected within 30 days prior to onset of treatment

AND

5 Submission of medical records (e.g., chart notes, laboratory values) documenting that patient is without decompensated liver disease (defined as Child-Pugh Class B or C) [1]

AND

6 One of the following:

6.1 Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

OR

6.2 Patient has demonstrated intolerance to interferon or ribavirin requiring discontinuation of triple therapy including Sovaldi plus peginterferon alfa plus ribavirin

Notes	*Refer to Background Section for alternative scoring equivalents.

3 . Background

Clinical Practice Guidelines

Comparison of Scoring Systems for Histological Stage (Fibrosis)

METAVIR	Batts-Ludwig	Knodell	Ishak
0	0	0	0
1	1	1	1
1	1	1	2
2	2	--	3
3	3	3	4
4	4	4	5
4	4	4	6

4 . Endnotes

A. Based on the 2014 AASLD/IDSA Treatment Guidelines, it may be advisable to delay treatment for some patients with documented early fibrosis stage (F 0-2), because waiting for future highly effective, pangenotypic, DAA combinations in IFN-free regimens may be prudent. [3]
B. Patients who use illicit drugs should receive continued support from drug abuse and psychiatric counseling services as an important adjunct to treatment of HCV infection. [4]
C. An interim analyses of a phase II trial (COSMOS) found that simeprevir and sofosbuvir for 12 or 24 weeks resulted in SVR12 rates of 79% to 96% with RBV and 93% without RBV in prior null responders to PegIFN and RBV with HCV genotype 1 and METAVIR scores of F0 to F2 (cohort 1). In addition, SVR4 rates were 96% with RBV and 100% without RBV in treatment-naïve and prior null responder patients with HCV genotype 1 and METAVIR scores of F3 or F4 (cohort 2). [6]

5 . References

1. Olysio Prescribing Information. Janssen Therapeutics, December 2013.
2. Per clinical consultation with hepatologist, March 11, 2014.

3. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. January 2014. http://www.hcvguidelines.org/full-report-view. Accessed March 13, 2014.
4. Ghany MG, Strader DB, Thomas DL, Seeff LB, American Association for the Study of Liver Diseases. Diagnosis, management, and treatment of hepatitis C: an update. Hepatology. 2009;49(4):1335-74.
5. Jacobson IM, Gordon SC, Kowdley KV, et al. Sofosbuvir for hepatitis C genotype 2 or 3 in patients without treatment options. N Engl J Med. 2013;368:1867-77.
6. Jacobson IM, Ghalib R, Rodriguez-Torres M, et al. SVR results of a once-daily regimen of simeprevir (SMV, TMC435) plus sofosbuvir (SOF, GS-7977) with or without ribavirin in cirrhotic and non-cirrhotic HCV genotype 1 treatment-naïve and prior null responder patients: the COSMOS study. Oral presentation presented at the 64th Annual Meeting of the American Association for the Study of Liver Diseases (AASLD); November 1-5, 2013c; Washington, DC.
7. Department of Veterans Affairs National Hepatitis C Resource Center Program and the Office of Public Health. Chronic hepatitis C virus (HCV) infection: treatment considerations. May 2014. http://www.hepatitis.va.gov/provider/guidelines/2014hcv/index.asp. Accessed June 25, 2014.