VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

Olysio® (simeprevir capsules –Janssen)

Effective Date:7/24/2018
Date Developed: 7/24/2018 by Catherine Sanders, MD and ESI P&T
Date Approved by P&T Committee:7/24/2018, 1/22/19
(Formulary Exclusion- For Exception Review Use Only)
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Olysio is a hepatitis C virus (HCV) NS3/4A protease inhibitor (PI) indicated for the treatment of chronic HCV infection as a component of a combination antiviral treatment regimen.
Recommended Authorization Criteria
Coverage of Olysio is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Chronic Hepatitis C Virus (HCV) Genotype 1.** Approve Olysio for the specified duration in patients that meet the all of following criteria (A, B, C, D and E):
   - **A)** The patient is ≥ 18 years of age; AND
   - **B)** Olysio is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
   - **C)** For patients with genotype 1a, the patient does not have the Q80K polymorphism (Note: testing for the Q80K polymorphism is not required for patients with genotype 1b); AND
   - **D)** The patient has a fibrosis score of ≥ 2, AND
   - **E)** The patient meets ONE of the following conditions (i or ii):
     - **i.** **Approve for 12 weeks** if Olysio will be prescribed in combination with Sovaldi AND the patient does not have cirrhosis; OR
     - **ii.** **Approve for 24 weeks if** Olysio will be prescribed in combination with Sovaldi AND the patient has cirrhosis.

Other Uses with Supportive Evidence

2. **Recurrent Hepatitis C Virus (HCV) Post-Liver Transplantation, Genotype 1.** Approve Olysio for 12 weeks in patients who meet all of the following criteria (A, B, C, D and E):
   - **A)** The patient is ≥ 18 years of age; AND
   - **B)** The patient has genotype 1 recurrent hepatitis C virus (HCV) after a liver transplantation; AND

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C) Olysio is prescribed by or in consultation with one of the following prescribers who is affiliated with a liver transplant center, a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND

D) If the patient has genotype 1a, the patient does not have the Q80K polymorphism (Note: testing for the Q80K polymorphism is not required for patients with genotype 1b); AND

E) Olysio is prescribed **in combination with Sovaldi.**

AASLD guidelines offer Olysio as an alternative regimen in patients with genotype 1 recurrent HCV post liver transplantation with compensated disease (Sovaldi + Olysio ± weight-based ribavirin [WBR] for 12 weeks [Class I, Level B]).

3. Patient Has Been Started on Olysio. Approve for an indication or condition addressed as an approval in the Recommended Authorization Criteria section (FDA-Approved Indications) or other use with supportive evidence to complete a course of therapy. Authorization for Olysio should not exceed 24 weeks of therapy. For example if a patient is eligible for 12 weeks of therapy and has received 3 weeks of therapy, approve 9 weeks of therapy to complete the 12-week course.

Olysio is not approved for the following: Life Expectancy Less Than 12 Months Due to Non-Liver Related Comorbidities, Monotherapy with Olysio, Pediatric Patients (Age < 18 years), Patient Has Failed Therapy with Olysio or Another NS3/4A Protease Inhibitor for Hepatitis C Virus [HCV] (i.e., Incivek [telaprevir tablets] or Victrelis [boceprevir capsules]). [Note: this does not include patients who have discontinued Incivek or Victrelis due to an adverse reaction to Incivek or Victrelis. Failure includes prior null response, partial response, or relapse]

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