VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

Epclusa® (sofosbuvir/velpatasvir tablets – Gilead)

Effective Date:7/24/2018
Date Developed: 7/24/2018 by Catherine Sanders, MD and ESI P&T
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(Archived 1/22/19)

Epclusa is a fixed-dose combination of velpatasvir, a hepatitis C virus (HCV) NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor, indicated for the treatment of chronic HCV genotype 1 through 6 infection in adults.1 In patients without cirrhosis or with compensated cirrhosis, Epclusa is indicated alone. In patients with decompensated cirrhosis (Child-Pugh B or C), Epclusa is indicated in combination with ribavirin.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Epclusa is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications

1. **Chronic Hepatitis C Virus (HCV) Genotype 1, 2, 3, 4, 5, or 6, No Cirrhosis or Compensated Cirrhosis (Child-Pugh A).** Approve for 12 weeks if the patient meets all of the following criteria (A, B, CD, and E):
   - **A)** The patient is ≥ 18 years of age; AND
   - **B)** Epclusa is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
   - **C)** The patient has a fibrosis score of ≥ 2, AND
   - **D)** The patient has not been previously treated with Epclusa; AND
   - **E)** The patient does not have cirrhosis OR the patient has compensated cirrhosis (Child-Pugh A)

2. **Chronic Hepatitis C Virus (HCV) Genotype 1, 2, 3, 4, 5, or 6, Decompensated Cirrhosis (Child-Pugh B or C).** Approve for the specified duration if the patient meets all of the following criteria (A, B, C, D, D and F):
   - **A)** The patient is ≥ 18 years of age; AND
   - **B)** Epclusa is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
   - **C)** The patient has a fibrosis score of ≥ 2, AND
   - **D)** The patient has not been previously treated with Epclusa or Vosevi; AND
   - **E)** The patient has decompensated cirrhosis (Child-Pugh B or C); AND
   - **F)** The patient meets one of the following criteria:

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i. The patient is ribavirin-eligible, according to the prescribing physician: Approve Epclusa for 12 weeks, if Epclusa is prescribed in combination with ribavirin; OR
ii. The patient is ribavirin-ineligible, according to the prescribing physician: Approve Epclusa for 24 weeks.

3. **Patient Has Been Started on Epclusa.** Approve for an indication or condition addressed as an approval in the Recommended Authorization Criteria section (FDA-Approved Indications or Other Uses with Supportive Evidence). Approve the duration described above to complete a course therapy (e.g., a patient who should receive 12 weeks, and has received 3 weeks should be approved for 9 weeks to complete their 12-week course).

Other Uses with Supportive Evidence

4. **Chronic Hepatitis C Virus, Genotype 1, 2, 3, 4, 5, or 6, Decompensated Cirrhosis (Child-Pugh B or C), Prior Null Responders, Prior Partial Responders, and Prior Relapsers to Epclusa or Vosevi.** Approve Epclusa for 24 weeks in patients who meet all of the following criteria (A, B, C, D, E and F).
   A) The patient is ≥18 years of age; AND
   B) Epclusa is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
   C) The patient has a fibrosis score of ≥2; AND
   D) The patient has been previously treated with Epclusa or Vosevi; AND
   E) The patient has decompensated cirrhosis (Childs-Pugh B or C); AND
   F) Epclusa will be prescribed **in combination with ribavirin.**

Epclusa is not approved for the following: Hepatitis C Virus (HCV) [any genotype], Combination with Any Other Direct-Acting Antivirals (DAAs) [Not Including Ribavirin]; Life Expectancy Less Than 12 Months Due to Non-Liver Related Comorbidities; Pediatric Patients (Age < 18 Years).

Revision History:

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