VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Hepatitis C – Epclusa Prior Authorization Policy
- Epclusa® (sofosbuvir/velpatasvir tablets and oral pellets – Gilead)
- sofosbuvir/velpatasvir tablets (authorized generic to Epclusa – Gilead)

REVIEW DATE: 06/09/2021; selected revision 06/16/2021

OVERVIEW

The fixed-dose combination of sofosbuvir, a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor, and velpatasvir, an HCV NS5A inhibitor, is indicated for the treatment of **chronic HCV genotype 1 through 6** infection in patients ≥ 3 years of age.[1] In patients with decompensated cirrhosis (Child-Pugh B or C), sofosbuvir/velpatasvir is administered with weight-based ribavirin. The FDA-approved duration of therapy with sofosbuvir/velpatasvir is 12 weeks for all patients.

Guidelines

American Association for the Study of Liver Diseases (AASLD) recommendations provide a simplified treatment algorithm for treatment-naïve adults. In treatment-naïve adults without cirrhosis the recommended regimens are Mavyret® (glecaprevir/pibrentasvir tablets) for 8 weeks or sofosbuvir/velpatasvir for 12 weeks. In treatment-naïve adults with compensated cirrhosis, the recommended regimens are Mavyret for 8 weeks (genotypes 1 through 6) or sofosbuvir/velpatasvir for 12 weeks (genotypes 1, 2, 4, 5, or 6; patients with genotype 3 require baseline NS5A resistance-associated substitution testing and those without Y93H can be treated with 12 weeks of sofosbuvir/velpatasvir). Additional genotype-specific and/or special circumstance-specific recommendations are also provided. Although Vosevi® (sofosbuvir/velpatasvir/voxilaprevir tablets) is recommended in most instances for adults with no cirrhosis or compensated cirrhosis who have failed treatment with a sofosbuvir-containing regimen, sofosbuvir/velpatasvir is recommended in adults (genotypes 1 through 6) with decompensated cirrhosis who have failed therapy with a sofosbuvir-containing regimen. In this setting, AASLD guidelines recommend sofosbuvir/velpatasvir for 24 weeks in combination with ribavirin. Data are limited to one Phase II study where sofosbuvir/velpatasvir was studied in patients with genotype 1, 2, and 3 who did not respond to velpatasvir-containing regimens including sofosbuvir/velpatasvir and Vosevi.[2,6] Retreatment with sofosbuvir/velpatasvir + ribavirin for 24 weeks yielded high overall response rates (sustained virologic response 12 weeks post-treatment [SVR12] 91% [n = 63/69]). Among patients with genotype 1 chronic HCV, 97% of patients (n = 36/37) achieved SVR12. In patients with genotype 2 chronic HCV, SVR12 was attained in 95% of patients (n = 13/14) and in patients with genotype 3 chronic HCV, SVR12 was attained in 78% of patients (n = 14/18). Baseline NS5A resistance associated substitutions did not appear to effect SVR rates. No breakdown of the proportion of patients with decompensated cirrhosis was provided in the study.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of sofosbuvir/velpatasvir. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with sofosbuvir/velpatasvir as well as the monitoring required for adverse events and efficacy, approval requires sofosbuvir/velpatasvir to be prescribed by or in consultation with a with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of sofosbuvir/velpatasvir is recommended in those who meet the following criteria:

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 the following criteria (A, B, C, and D):
   - **A)** Patient is ≥ 3 years of age; AND
   - **B)** Patient meets ONE of the following conditions (i or ii):
     - **i.** Patient does not have cirrhosis; OR
     - **ii.** Patient has compensated cirrhosis (Child-Pugh A); AND
   - **C)** Patient has not been previously treated with sofosbuvir/velpatasvir; AND
   - **D)** The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

2. **Chronic Hepatitis C Virus (HCV) Genotype 1, 2, 3, 4, 5, or 6, Decompensated Cirrhosis (Child-Pugh B or C), Adult.** Approve for the duration below if the patient meets all of the following criteria (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has decompensated cirrhosis (Child-Pugh B or C); AND
   - **C)** Patient meets ONE of the following conditions (i or ii):
     - **i.** Patient is ribavirin-eligible, according to the prescriber: Approve for 12 weeks, if the medication is prescribed in combination with ribavirin; OR
     - **ii.** Patient is ribavirin-ineligible, according to the prescriber: Approve for 24 weeks; AND
   - **D)** The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

3. **Chronic Hepatitis C Virus (HCV) Genotype 1, 2, 3, 5, 6, or 6, Decompensated Cirrhosis (Child-Pugh B or C), Pediatric Patient.** Approve for 12 weeks if the patient meets the following criteria (A, B, C, and D):
   - **A)** Patient is ≥ 3 years of age and < 18 years of age; AND
   - **B)** Patient has decompensated cirrhosis (Child-Pugh B or C); AND
   - **C)** The medication will be prescribed in combination with ribavirin; AND
   - **D)** The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

Other Uses with Supportive Evidence

4. **Chronic Hepatitis C Virus (HCV), Genotype 1, 2, 3, 4, 5, or 6, Decompensated Cirrhosis (Child-Pugh B or C), Prior Null Responder, Prior Partial Responder, and Prior Relapser to sofosbuvir/velpatasvir or Vosevi**. Approve for 24 weeks if the patient meets the following criteria (A, B, C, D, and E):
   - **A)** Patient is ≥ 3 years of age; AND
   - **B)** Patient has decompensated cirrhosis (Child-Pugh B or C); AND
   - **C)** Patient meets ONE of the following conditions (i or ii):
     - **i.** Patient has been previously treated with sofosbuvir/velpatasvir; OR
     - **ii.** Patient has previously been treated with Vosevi; AND
   - **D)** The medication will be prescribed in combination with ribavirin; AND
   - **E)** The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

5. **Patient Has Been Started on sofosbuvir/velpatasvir.** 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).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of sofosbuvir/velpatasvir is not recommended in the following situations:

1. **Hepatitis C Virus (HCV) [any genotype], Combination with Any Other Direct-Acting Antivirals (DAAs) [Not Including Ribavirin].** Sofosbuvir/velpatasvir provides a complete antiviral regimen for patients with genotype 1 HCV. Sofosbuvir/velpatasvir is not recommended to be used with other products containing sofosbuvir.

2. **Life Expectancy Less Than 12 Months Due to Non-Liver Related Comorbidities.** Patients with a limited life expectancy that cannot be remediated by HCV treatment, liver transplantation, or another directed therapy do not require antiviral treatment. Patients with a short life expectancy owing to liver disease should be managed in consultation with an expert. Little evidence exists to support initiation of HCV treatment in patients with a limited life expectancy (< 12 months) owing to non-liver-related comorbid conditions. For these patients, the benefits of HCV treatment are unlikely to be realized and palliative care strategies should take precedence.

3. **Pediatric Patient (< 3 Years of Age).** The safety and efficacy of sofosbuvir/velpatasvir have not been established in pediatric patients < 3 years of age.[1]

4. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Epclusa® tablets [prescribing information]. Foster City, CA: Gilead; June 2021.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Testing, managing, and treating hepatitis C. Available at: http://www.hcvguidelines.org. Updated January 21, 2021. Accessed on June 2, 2021.
3. Gane EJ, Shiffman ML, Etzkorn K, et al. Sofosbuvir-velpatasvir with ribavirin for 24 weeks in HCV patients previously treated with a direct-acting antiviral regimen. *Hepatology*. 2017;66(4):1083-1089.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	06/17/2020
Annual Revision	Throughout the policy, where listed, "Epclusa (brand or generic)" was changed to "sofosbuvir/velpatasvir". **Chronic Hepatitis C Virus (HCV) Genotype 1, 2, 3, 4, 5, or 6, Decompensated Cirrhosis (Child-Pugh B or C), Adult:** Prescribing physician was changed to prescriber.	06/09/2021
Selected Revision	Epclusa oral pellets added to policy. **Chronic Hepatitis C Virus (HCV) Genotype 1, 2, 3, 4, 5, or 6, No Cirrhosis or Compensated Cirrhosis (Child-Pugh A):** Age of approval was changed to ≥ 3 years of age. **Chronic Hepatitis C Virus (HCV) Genotype 1, 2, 3, 5, 6, or 6, Decompensated Cirrhosis (Child-Pugh B or C), Pediatric Patient:** Age of approval was changed to ≥ 3 years of age and < 18 years of age. **Chronic Hepatitis C Virus (HCV), Genotype 1, 2, 3, 4, 5, or 6, Decompensated Cirrhosis (Child-Pugh B or C), Prior Null Responder, Prior Partial Responder, and Prior Relapser to sofosbuvir/velpatasvir or Vosevi.** Age of approval was changed to ≥ 3 years of age. **Pediatric Patient (Age < 6 Years or < 17 kg):** The age was revised to < 3 years of age and weight was removed from this "Condition not Recommended for Approval".	06/16/2021