

DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

- POLICY:** Hepatitis C – Epclusa Drug Quantity Management Policy – Per Days
- Epclusa® (sofosbuvir/velpatasvir tablets and oral pellets – Gilead)
 - Sofosbuvir/velpatasvir tablets (authorized generic to Epclusa 400 mg/100 mg tablets – Gilead)

REVIEW DATE: 08/31/2022

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

Dosing

The FDA-approved duration of therapy with sofosbuvir/velpatasvir is 12 weeks for all patients.¹ In patients with decompensated cirrhosis (Child-Pugh B or C), sofosbuvir/velpatasvir is administered with weight-based ribavirin.

In adults, the recommended dose is one tablet (400 mg/100 mg) once daily (QD).¹ In pediatric patients ≥ 3 years of age, dosing is weight-based (Table 1).

Table 1. Dosing in Pediatric Patients ≥ 3 Years of Age.²

Body weight	Sofosbuvir/velpatasvir daily dose	Dosing of Epclusa oral pellets	Dosing of sofosbuvir/velpatasvir tablet (Epclusa, generic)
< 17 kg	150 mg/37.5 mg per day	One 150 mg/37.5 mg packet of pellets QD	N/A
≥ 17 to < 30 kg	250 mg/50 mg per day	One 200 mg/50 mg packet of pellets QD	One 200 mg/50 mg tablet QD
≥ 30 kg	400 mg/100 mg per day	Two 200 mg/50 mg packet of pellets QD	One 400 mg/100 mg tablet QD*

QD – Once daily; N/A – Not applicable; *Two 200 mg/50 mg tablets once daily (QD) can be used for patients who cannot swallow the 400 mg/100 mg tablet.

Availability

Sofosbuvir/velpatasvir (Epclusa, generic) is available as a fixed-dose combination tablet of sofosbuvir 400 mg/velpatasvir 100 mg.¹ Epclusa (brand only) is also available as fixed-dose combination tablet of sofosbuvir 200 mg/velpatasvir 50 mg as well as film-coated oral pellets of sofosbuvir 200 mg/velpatasvir 50 mg and sofosbuvir 150 mg/velpatasvir 37.5 mg.

Guidelines

American Association for the Study of Liver Diseases (AASLD) recommendations provide information regarding a longer duration of treatment (beyond 12 weeks) for certain circumstances.² 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.^{2,3} Retreatment

08/31/2022

© 2022. All Rights Reserved.

This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

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 impact SVR rates. No breakdown of the proportion of patients with decompensated cirrhosis was provided in the study.

POLICY STATEMENT

This Drug Quantity Management program has been developed to prevent stockpiling, misuse and/or overuse of sofosbuvir/velpatasvir (Epclusa, generic). If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for the duration noted below.

Automation: None.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per 365 Days*	Home Delivery Maximum Quantity per 365 Days
Epclusa® (sofosbuvir/velpatasvir tablets [generic for 400mg/100 mg tablets only] and oral pellets)	400 mg/100 mg tablets	84 tablets	84 tablets
	200 mg/50 mg tablet	84 tablets	84 tablets
	200 mg/50 mg oral pellets	84 pellet packets	84 pellet packets
	150 mg/37.5 mg pellets	84 pellet packets	84 pellet packets

*This is enough drug for patient to complete a 12-week course of therapy based on approved dosing. Patients who weigh > 30 kg and require two pellet packets should use the 400 mg/100 mg tablets.

CRITERIA

Sofosbuvir/velpatasvir 400 mg/100 mg tablet (Epclusa 400 mg/100 mg tablet, generic), Epclusa 200 mg/50 mg tablet

1. **Chronic Hepatitis C Virus (HCV) Genotype 1, 2, 3, 4, 5, or 6, Decompensated Cirrhosis (Child-Pugh B or C), Adult.** Approve 168 tablets per 365 days at retail or home delivery if the patient meets the following criteria (A, B, and C):
 - A. Patient has not been previously treated with sofosbuvir/velpatasvir (Epclusa, generic) or Vosevi.
Note: For patients previously treated with sofosbuvir/velpatasvir (Epclusa, generic) or Vosevi see *Criterion 2* below; AND
 - B. Patient has decompensated cirrhosis (Child-Pugh B or C); AND
 - C. Patient is ribavirin-ineligible, according to the prescriber.
2. **Chronic Hepatitis C Virus, 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 (Epclusa, generic) or Vosevi.** Approve 168 tablets per 365 days at retail or home delivery if the patient meets all of the following criteria (A, B, and C):
 - A. Patient has been previously treated with sofosbuvir/velpatasvir (Epclusa, generic) or Vosevi; AND
 - B. Patient has decompensated cirrhosis (Child-Pugh B or C); AND
 - C. The medication will be prescribed in combination with ribavirin.
3. For an indication or condition addressed as an approval in the above criteria section, approve the quantity requested, not to exceed 168 tablets per 365 days at retail or home delivery to complete a

course therapy. Note: If the patient has received 3 weeks of therapy (21 tablets), approve 147 tablets to complete 24 weeks of treatment.

Epclusa 150 mg/37.5 mg pellet packets

- 1. Chronic Hepatitis C Virus, 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 (Epclusa, generic) or Vosevi.** Approve 168 pellet packets per 365 days at retail or home delivery if the patient meets all of the following criteria (A, B, and C):
 - A.** Patient has been previously treated with sofosbuvir/velpatasvir (Epclusa, generic) or Vosevi; **AND**
 - B.** Patient has decompensated cirrhosis (Child-Pugh B or C); **AND**
 - C.** The medication will be prescribed in combination with ribavirin.
- 2.** For an indication or condition addressed as an approval in the above criteria section, approve the quantity requested, not to exceed 168 pellet packets per 365 days at retail or home delivery, to complete a course therapy.

Note: If the patient has received 3 weeks of therapy (21 pellet packets), approve 147 pellet packets to complete 24 weeks of treatment.

Epclusa 200 mg/50 mg pellet packets

- 1. Chronic Hepatitis C Virus, 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 (Epclusa, generic) or Vosevi.** Approve 336 pellet packets per 365 days at retail or home delivery if the patient meets all of the following criteria (A, B, and C):
 - A.** Patient has been previously treated with sofosbuvir/velpatasvir (Epclusa, generic) or Vosevi; **AND**
 - B.** Patient has decompensated cirrhosis (Child-Pugh B or C); **AND**
 - C.** The medication will be prescribed in combination with ribavirin.
- 2.** For an indication or condition addressed as an approval in the above criteria section, approve the quantity requested, not to exceed 336 pellet packets per 365 days at retail or home delivery, to complete a course therapy.

Note: If the patient has received 3 weeks of therapy (21 pellet packets), approve 147 pellet packets to complete 24 weeks of treatment.

REFERENCES

1. Epclusa® tablets and oral pellets [prescribing information]. Foster City, CA: Gilead; April 2022.
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 October 5, 2021. Accessed on August 26, 2022.
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.

