

**CRITERIA FOR PRIOR AUTHORIZATION**

Epclusa® (sofosbuvir/velpatasvir)

**PROVIDER GROUP** Pharmacy**MANUAL GUIDELINES** The following drug requires prior authorization:  
Sofosbuvir/Velpatasvir (Epclusa®)**CRITERIA FOR INITIAL APPROVAL OF SOFOSBUVIR/VELPATASVIR:** (must meet all of the following)*\*Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of up to 12 weeks of Sofosbuvir/Velpatasvir therapy total)\**

- Patient must have a diagnosis of chronic hepatitis C (CHC)
- Patient must have genotype 1, 2, 3, 4, 5, or 6 hepatitis C
- Patient must not have severe renal impairment (eGFR<30mL/min/1.73m<sup>2</sup>) or currently require hemodialysis
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist
- Patient must be 18 years of age or older
- Patient must not have been on previous or concurrent direct acting hepatitis C agents
- Patient must not have a history of illicit substance use or alcohol abuse within the past 6 months
- Patient has a pre-treatment HCV RNA level drawn and results are submitted with PA request
- Dose must not exceed 1 tablet per day
- Patient must have one of the following:
  - Advanced fibrosis (as defined by a Metavir score of F3)
  - Cirrhosis
  - Organ transplant
  - Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g., vasculitis)
  - Proteinuria
  - Nephrotic syndrome
  - Membranoproliferative glomerulonephritis
- Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment with sofosbuvir/velpatasvir therapy
- If the patient has decompensated cirrhosis, sofosbuvir/velpatasvir must be used in combination with ribavirin
- If the patient has compensated cirrhosis, sofosbuvir/velpatasvir must *not* be used in combination with ribavirin
- Patient must not be on concurrent:
  - Amiodarone
  - Moderate to strong inducers of CYP2B6 (e.g., carbamazepine, fosphenytoin, nevirapine, phenobarbital, phenytoin, primidone, rifampin)
  - Moderate to strong inducers of CYP2C8 (e.g., rifampin)
  - Moderate to strong inducers of CYP3A4 (e.g., avasimibe, carbamazepine, dexamethasone, ethosuximide, griseofulvin, phenytoin, primidone, progesterone, rifabutin, rifampin, nafcillin, nelfinavir, nevirapine, oxcarbazepine, phenobarbital, phenylbutazone, St John's wort, sulfadimidine, sulfapyrazone, troglitazone)
  - Inducers of P-gp (e.g., avasimibe, carbamazepine, phenytoin, rifampin, St John's wort, tipranavir/ritonavir)
- For Genotypes 1 and/or 4: the PDL preferred drug, which covers Genotypes 1 and 4, is required unless the patient has a documented clinical rationale for using the non-preferred agent supported by the label or AASLD/IDSA HCV guidelines

PA Criteria

**RENEWAL CRITERIA FOR SOFOSBUVIR/VELPATASVIR:**

- Prescriber must document adherence by patient of greater than or equal to 90%

**LENGTH OF APPROVAL FOR SOFOSBUVIR/VELPATASVIR: 4 weeks for a total of 12 weeks of treatment**

Notes:

- No patients with genotype 5 were enrolled in the trial to determine decompensated cirrhosis outcomes.
- Treatment with Eplusa with ribavirin in patients with decompensated cirrhosis for 12 weeks resulted in numerically higher SVR12 rates than treatment of Eplusa alone for 12 weeks for 24 weeks.

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR

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PHARMACY PROGRAM MANAGER  
DIVISION OF HEALTH CARE FINANCE  
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

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