Sofosbuvir/Velpatasvir (EPCLUSA)
Criteria for Use
Updated June 2024

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National Formulary Committee Monograph on this drug at the *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive sofosbuvir/velpatasvir (SOF/VEL).

☐ Limited Life Expectancy

☐ Documented ongoing nonadherence to prescribed medications or medical treatment.

☐ Concurrent use of drugs not recommended with SOF/VEL (e.g., amiodarone, apalutamide, modafinil, rifamycins, CYP450 inducers, St John's Wort, > 10mg/day of rosuvastatin, efavirenz, etravirine). Recommend full drug-drug interaction check.[1]

☐ Hepatitis B surface antigen (HBsAg) positive and not on antiviral treatment with entecavir or tenofovir

☐ Contraindication to ribavirin (RBV) IF RBV is indicated[2]

Inclusion Criteria

All of the following criteria must be met.

☐ Care is provided by and/or in consultation with a VA/VA Community Care Hepatitis C virus (HCV) specialist.

☐ HCV Genotype (GT) 1-6 or ungenotyped with detectable HCV RNA

☐ Treatment regimen and duration consistent with HCV GT and patient characteristics (see VA HCV Treatment Considerations)[3]

☐ Completed hepatitis B screening: at a minimum HBsAg, HBV core antibody (anti-HBc) and HBV surface antibody (anti-HBs)

☐ Adherence counseling performed including laboratory follow-up and documented understanding by patient.

Additional Inclusion Criteria

One of the following must be met.

☐ GT 1-6 or ungenotyped with detectable HCV RNA and treatment naïve with or without compensated cirrhosis (CTP A)[4]

☐ GT 1-6 and treatment experienced (PEG-IFN/RBV +/- NS3/4A inhibitor but NS5A and SOF naïve) with or without compensated cirrhosis (CTP A)

☐ GT 1b, treatment-experienced (NS5A naïve and SOF-experienced)[5]

☐ GT 1-6 with decompensated cirrhosis (CTP B or C) 12 weeks with RBV or 24 weeks without RBV if NS5A naïve or 24 weeks with RBV if NS5A-experienced

Footnotes

[1]See product labeling, HCV Treatment considerations or Liverpool HEP drug interaction checker for complete list of drug-drug interactions

[2] Contraindication to RBV includes history of significant cardiac disease, significant anemia, pregnancy, and men whose female partner is pregnant or plans to become pregnant.

[3]Recommended regimen based on genotype, prior treatment, presence comorbidities (e.g., HIV or post-transplant) should use VA Hepatitis C Treatment considerations (*Hepatitis C Treatment Considerations - Viral Hepatitis and Liver Disease (va.gov)*) or IDSA/AASLD Guidelines (https://www.hcvguidelines.org)

[4] Ribavirin should be added if GT 3 with compensated cirrhosis and Y93H is present.

[5]if GT 1a, add RBV or use SOF/VEL/VOX

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