

# Ledipasvir / Sofosbuvir (HARVONI)

## 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 ledipasvir / sofosbuvir (LDV/SOF).**

- Limited life expectancy
- Documented ongoing nonadherence to prescribed medications or medical treatment.
- Concurrent use of drugs not recommended with LDV/SOF (e.g., cytochrome P450 inducers, amiodarone/dronaderone, rosuvastatin (> 10mg/day), high-dose proton pump inhibitors, and others). Recommend full drug-drug interaction check.<sup>1</sup>
- Hepatitis B surface antigen (HBsAg) positive and not on antiviral treatment with entecavir or tenofovir
- Contraindication to ribavirin (RBV) IF RBV is indicated<sup>2</sup>

### 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 specialist.
- HCV genotype (GT) 1, 4, 5 or 6
- Treatment regimen and duration consistent with HCV GT and patient characteristics (see VA HCV Treatment considerations)<sup>3</sup>
- Completed hepatitis B screening: at 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, 4, 5 or 6, treatment-naïve with or without compensated cirrhosis
- GT 1, 4, 5 or 6, treatment-naïve with decompensated cirrhosis and no contraindication to ribavirin<sup>2</sup>
- GT 1, treatment-experienced (pegylated interferon or NS3/4A inhibitor only) with decompensated cirrhosis and no contraindication to ribavirin<sup>2</sup>

### Supplemental Information

#### Footnotes

<sup>1</sup>See product labeling, HCV Treatment considerations or Liverpool HEP drug interaction checker for complete list of drug-drug interactions

<sup>2</sup> Contraindication to RBV includes history of significant cardiac disease, significant anemia, pregnancy, and men whose female partner is pregnant or plans to become pregnant

<sup>3</sup>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>)