Reference number(s)
Policy: 2134-A
Qsets: 5920-A, 6284-A

Specialty Guideline Management ledipasvir-sofosbuvir, Harvoni

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Harvoni	ledipasvir-sofosbuvir

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1,2]

Harvoni is indicated for the treatment of adults and pediatric patients 3 years of age and older with chronic hepatitis C virus (HCV):

- Genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis
- Genotype 1 infection with decompensated cirrhosis, for use in combination with ribavirin
- Genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, for use in combination with ribavirin

All other indications are considered experimental/investigational and not medically necessary.

Prescriber Specialties

This medication must be prescribed by or in consultation with a provider experienced in the management of hepatitis C virus infection.

Coverage Criteria

Hepatitis C virus infection, without ribavirin[1-5]

Genotype 1 infection

- Authorization of up to 12 weeks total may be granted for treatment-naïve members with compensated cirrhosis.
- Authorization of up to 12 weeks total may be granted for treatment-naïve members without cirrhosis when any of the following criteria is met:
    - Member is less than 18 years of age
    - Member has human immunodeficiency virus (HIV) co-infection
    - Member has pre-treatment HCV RNA greater than or equal to 6 million IU/mL
- Authorization of up to 8 weeks total may be granted for treatment-naive members without cirrhosis who have pre-treatment HCV RNA below 6 million IU/mL and do not have HIV co-infection.
- Authorization of up to 12 weeks total may be granted for members without cirrhosis who failed prior treatment with peginterferon alfa (PEG-IFN) with or without ribavirin (RBV) with or without an HCV protease inhibitor.
- Authorization of up to 24 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with PEG-IFN with or without RBV with or without an HCV protease inhibitor.

Genotype 4 or 5 infection

Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis who are treatment-naïve or who failed prior treatment with PEG-IFN with or without RBV with or without an HCV protease inhibitor.

Genotype 6 infection

Authorization of up to 12 weeks total may be granted for members without cirrhosis or with compensated cirrhosis when either of the following criteria is met:

- Member is treatment-naïve and does not have genotype 6e subtype.
- Member has failed prior treatment with PEG-IFN with or without RBV with or without an HCV protease inhibitor.

Decompensated cirrhosis (Child Turcotte Pugh [CTP] class B or C)

Authorization of up to 24 weeks total may be granted for members with HCV genotype 1, 4, 5, or 6 infection who have decompensated cirrhosis and documented anemia (baseline hemoglobin [Hgb] below 10 g/dL) or RBV ineligibility (see Appendix).

Recurrent HCV infection post liver transplantation

Authorization of up to 12 weeks total may be granted for members with recurrent HCV genotype 1, 4, 5, or 6 infection post liver transplantation without cirrhosis or with compensated cirrhosis.

Kidney transplant recipients

Authorization of up to 12 weeks total may be granted for members with HCV genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis who are treatment-naïve or who have not failed prior treatment with a direct-acting antiviral.

Hepatitis C virus infection, in combination with ribavirin[1-5]

Genotype 1 infection

Authorization of up to 12 weeks total may be granted for members with compensated cirrhosis who failed prior treatment with PEG-IFN with or without RBV with or without an HCV protease inhibitor.

Decompensated cirrhosis (CTP class B or C)

- Authorization of up to 12 weeks total may be granted for members with HCV genotype 1, 4, 5, or 6 infection and decompensated cirrhosis.
- Authorization of up to 24 weeks total may be granted for members with HCV genotype 1, 4, 5, or 6 infection and decompensated cirrhosis who failed prior treatment with a sofosbuvir-based regimen (e.g., sofosbuvir and RBV, sofosbuvir plus PEG-IFN and RBV, sofosbuvir plus simeprevir with or without RBV).

Recurrent HCV infection post liver transplantation

- Authorization of up to 12 weeks total may be granted for treatment-naïve members with recurrent HCV genotype 1, 4, 5, or 6 infection post liver transplantation and decompensated cirrhosis.
- Authorization of up to 24 weeks total may be granted for treatment experienced members with recurrent HCV genotype 1, 4, 5, or 6 infection post liver transplantation and decompensated cirrhosis.
- Authorization of up to 12 weeks total may be granted for members with HCV genotype 1 or 4 infection post liver transplantation without cirrhosis or with compensated cirrhosis who are treatment naïve or have failed prior treatment with PEG-IFN with or without RBV with or without an HCV protease inhibitor.

Hepatitis C Virus and HIV coinfection[1,2,5]

Authorization may be granted for members with HCV and HIV coinfection when the criteria for approval of

the requested regimen in the coverage criteria above are met.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

Other

- Member must be 3 years of age or older.
- Some elements outlined in this policy may not be enforced for certain plans due to regulatory guidelines.
- The following information may be requested to support regulatory requirements and will not be used to decision individual requests:
    - Treatment status (i.e., treatment-naïve or retreatment)
    - For initial treatment: confirmation of member readiness
    - For retreatment: reason for the need for retreatment (e.g., prior treatment failure, reinfection), confirmation of member readiness, and ability to adhere to proposed treatment plan
    - Hepatitis B virus screening results
    - Metavir/Fibrosis score

Appendix: Ribavirin (RBV) Ineligibility[3,4]

Ribavirin (RBV) ineligibility is defined as one or more of the below:

- Intolerance to RBV
- Pregnant female or male whose female partner is pregnant
- Hemoglobinopathy
- Coadministration with didanosine
- History of significant or unstable cardiac disease

References

1. Harvoni [package insert]. Foster City, CA: Gilead Sciences; December 2024.
2. Ledipasvir and sofosbuvir tablet [package insert]. Foster City, CA: Asegua Therapeutics LLC; March 2020.
3. Ribavirin capsules [package insert] . East Windsor, NJ: Aurobindo Pharma USA, Inc.; July 2023.

4. Ribavirin tablets [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; May 2023.
5. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. https://www.hcvguidelines.org. Last changes made December 19, 2023. Accessed August 8, 2024.