

Specialty Guideline Management

ribavirin

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
ribavirin (all brands)	ribavirin

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}

- Ribavirin capsules are indicated in combination with interferon alfa-2b (pegylated and nonpegylated) for the treatment of chronic hepatitis C (CHC) in patients 3 years of age and older with compensated liver disease.
- Ribavirin tablets are indicated for the treatment of chronic hepatitis C (CHC) virus infection in combination with Pegasys in patients 5 years of age and older with compensated liver disease not previously treated with interferon alfa, and in adult CHC patients coinfecting with human immunodeficiency virus (HIV).

Compendial Uses^{11,12}

Chronic hepatitis E virus infection

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

Exclusions

Exclusions to other antiviral drugs being used in combination with the requested drug apply. Refer to the SGM policy for each drug in the treatment regimen for applicable exclusions.

Coverage Criteria

Hepatitis C virus (HCV) infection¹⁻¹⁰

Refer to the SGM of requested regimen for the specific criteria for approval and approval durations.

Hepatitis E virus (HEV) infection in organ transplant recipients^{11,12}

Authorization of 12 months may be granted for members with chronic hepatitis E virus (HEV) infection in organ transplant recipients.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy for chronic hepatitis E virus (HEV) infection must meet all criteria in the Coverage Criteria.

Other

Some elements outlined in this policy may not be enforced for certain plans due to regulatory guidelines.

References

1. Ribavirin capsules [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; July 2023.
2. Ribavirin tablets [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; May 2023.
3. Epclusa [package insert]. Foster City, CA: Gilead Sciences, Inc.; April 2022.
4. Harvoni [package insert]. Foster City, CA: Gilead Sciences; March 2020.
5. Mavyret [package insert]. North Chicago, IL: AbbVie Inc.; October 2023.
6. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; March 2020.
7. Viekira Pak [package insert]. North Chicago, IL: AbbVie Inc.; December 2019.
8. Vosevi [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2019.
9. Zepatier [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; May 2022.

Reference number(s)
Policy:2140-A
Qset: 5920-A, 6284-A

10. 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.
11. European Association for the Study of the Liver. EASL clinical practice guidelines on hepatitis E virus infection. J Hepatol. 2018;68(6):1256-1271.
12. Te H, Doucette K. Viral hepatitis: Guidelines by the American Society of Transplantation Infectious Disease Community of Practice. Clin Transplant. 2019;33(9):e13514. doi: 10.1111/ctr.13514.