

PRIOR AUTHORIZATION POLICY

POLICY: Antivirals – Ribavirin (Oral Products) Prior Authorization Policy

- ribavirin tablets (generic)
- ribavirin capsules (generic)

REVIEW DATE: 06/19/2024

OVERVIEW

The ribavirin products included in this Prior Authorization policy are indicated for use **in combination with pegylated interferons or interferon for the treatment of chronic hepatitis C virus (HCV)** in adults and children with compensated disease. Ribavirin remains a component of some regimens for the management of HCV; however, there is no role for interferon (specifically non-pegylated interferon) in the management of HCV.² The specific indications vary slightly among the oral ribavirin products:

- Ribavirin capsules are indicated in combination with PegIntron[®] (peginterferon alfa-2b injection) or Intron A[®] (interferon alfa-2b injection) for the treatment of chronic HCV in patients ≥ 3 years of age with compensated liver disease.¹
- Ribavirin tablets are indicated in combination with Pegasys[®] (peginterferon alfa-2a) for the treatment of patients ≥ 5 years of age with chronic HCV with compensated liver disease who have not previously been treated with interferon alfa, and in adults with chronic HCV co-infected with human immunodeficiency virus.⁷

Ribavirin is an antiviral agent with direct antiviral activity in tissue culture against many RNA viruses.¹ Ribavirin increases the mutation frequency in the genomes of several viruses and ribavirin triphosphate inhibits HCV polymerase in a biochemical reaction.

According to the Centers for Disease Control and Prevention, oral ribavirin has been used off-label to treat other systemic viral infections including, but not limited to, Lassa fever^{5,6}, Nipah virus¹³, West Nile virus¹⁴, and Crimean Congo hemorrhagic fever.^{4,12} In addition, oral ribavirin has a place in therapy for the management of respiratory syncytial virus in transplant recipients.³

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of ribavirin. The intent of this Prior Authorization program is to ensure ribavirin is not used in the absence of pegylated interferon or a direct-acting antiviral for the treatment of HCV. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients being treated with ribavirin, as well as the monitoring required for adverse events and efficacy, approval requires ribavirin (for hepatitis C indications) to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: Automation is in place for the use of a pegylated interferon or a direct-acting antiviral for HCV in the past 130 days. This is used as a surrogate marker for HCV. If the criteria for prior use of a pegylated interferon or direct-acting antiviral for HCV are not met at the point-of-service, coverage will be determined by Prior Authorization criteria.

RECOMMENDED AUTHORIZATION CRITERIA

06/19/2024

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Coverage of ribavirin is recommended in those who meet one of the following criteria:

FDA-Approved Indication

1. **Hepatitis C Virus (HCV).** Approve for 1 year if the patient meets BOTH of the following (A and B):
 - A) Patient meets ONE of the following (i or ii):
 - i. The medication is prescribed in combination with peginterferon alfa; OR
Note: Pegasys (pegylated interferon alfa-2a injection) is an example of a peginterferon alfa.
 - ii. The medication is prescribed in combination with a direct-acting antiviral for HCV; AND
Note: Examples of direct-acting antivirals for HCV include but are not limited to Epclusa (velpatasvir/sofosbuvir tablets), Sovaldi (sofosbuvir tablets/oral pellets), Harvoni (ledipasvir/sofosbuvir tablets/oral pellets), Zepatier (elbasvir/grazoprevir tablets).
 - B) The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, liver transplant physician, or infectious diseases physician.

Other Uses with Supportive Evidence

2. **Other Systemic Viral Infections, Excluding COVID-19 (Coronavirus Disease 2019).** Approve for 1 year.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of ribavirin is not recommended in the following situations:

1. **COVID-19 (Coronavirus Disease 2019).** Efficacy is not established.^{8,9} Ribavirin is not addressed as a treatment modality in guidelines from the Infectious Diseases Society of America or the National Institutes of Health.^{10,11}
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Ribavirin capsules [prescribing information]. East Windsor, NJ: Aurobindo Pharma; July 2023.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Testing, managing, and treating hepatitis C. Updated December 19, 2023. Available at: <http://www.hcvguidelines.org>. Accessed on June 3, 2024.
3. Shah JN and Chemaly RF. Management of RSV infection in adult recipients of hematopoietic stem cell transplantation. 2011;117:2755-2763.
4. Ergonul O, Keske S, Celdir MG, et al. Systematic review and meta-analysis of postexposure prophylaxis for Crimean-Congo Hemorrhagic Fever Virus among healthcare workers. *Emerg Infect Dis.* 2018;24(9):1642-1648.
5. Bausch DG, Hadi CM, Khan SH, Lertora JIL. Review of the literature and proposed guidelines for the use of oral ribavirin as postexposure prophylaxis for lassa fever. *Clin Infect Dis.* 2010;51(12):1435-1441.
6. Centers for Disease Control and Prevention. Lassa fever. Treatment. Last reviewed: April 19, 2024. Available at: https://www.cdc.gov/lassa-fever/about/?CDC_AAref_Val=https://www.cdc.gov/vhf/lassa/treatment/index.html. Accessed on June 3, 2024.
7. Ribavirin tablets [prescribing information]. East Windsor, NJ: Aurobindo Pharma; February 2024.
8. Hung IF, Lung KC, Tso EY, et al. Triple combination of interferon beta-1b, lopinavir-ritonavir, and ribavirin in the treatment of patients admitted to hospital with COVID-19: an open-label, randomised, Phase 2 trial. *Lancet.* 2020;395(10238):1695-1704.
9. Elalfy H, Besheer T, El-Mesery A, et al. Effect of a combination of nitazoxanide, ribavirin, and ivermectin plus zinc supplement (MANS.NRIZ study) on the clearance of mild COVID-19. *J Med Virol.* 2021;93(5):3176-3183.

10. Bhimraj A, Morgan RL, Hirsch Shumaker A, et al. Infectious Diseases Society of America Guidelines on the treatment and management of patients with COVID-19. Available at: <https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/>. Updated June 23, 2023. Accessed on June 4, 2024.
11. COVID-19 treatment guidelines panel. Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health. Available at <https://www.covid19treatmentguidelines.nih.gov/>. Updated June 3, 2024. Accessed June 3, 2024.
12. Centers for Disease Control and Prevention. Crimean-Congo Hemorrhagic Fever. Treatment. Last reviewed: March 5, 2024. Available at: <https://www.cdc.gov/vhf/crimean-congo/treatment/index.html>. Accessed on June 3, 2024.
13. Centers for Disease Control and Prevention. Nipah Virus. Treatment. Last reviewed: March 25, 2024. Available at: https://www.cdc.gov/nipah-virus/hcp/clinical-overview/?CDC_AAref_Val=https://www.cdc.gov/vhf/nipah/treatment/index.html. Accessed on June 3, 2024.
14. Centers for Disease Control and Prevention. West Nile Virus. Treatment and prevention. Last reviewed: May 15, 2024. Available at: <https://www.cdc.gov/west-nile-virus/hcp/treatment-prevention/therapeutics-review.html>. Accessed on June 3, 2024.