

PRIOR AUTHORIZATION POLICY

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

ribavirin tablets (generic)ribavirin capsules (generic)

REVIEW DATE: 06/18/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS, COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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 [obsolete]) or Intron A® (interferon alfa-2b injection [obsolete]) 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 virus¹², West Nile virus¹³, and Crimean Congo hemorrhagic fever.^{4,11} 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.

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

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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
 - <u>Note</u>: 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, infectious diseases physician, or liver transplant physician.

Other Uses with Supportive Evidence

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

CONDITIONS NOT COVERED

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

is(are) considered not medically necessary for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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.¹⁰

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.hcvquidelines.org. Accessed on June 12, 2025.
- 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 JJL. 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.
- Centers for Disease Control and Prevention. Lassa fever. Treatment. Last reviewed: January 31, 2025. Available at: https://www.cdc.gov/lassafever/about/?CDC_AAref_Val=https://www.cdc.gov/vhf/lassa/treatment/index.html. Accessed on June 12, 2025.
- 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 4, 2025. Accessed on June 4, 2024.
- 11. Centers for Disease Control and Prevention. Crimean-Congo Hemorrhagic Fever. Treatment. Last reviewed: March 5, 2024. Available at: https://www.cdc.gov/crimean-congo-hemorrhagic/about/?CDC_AAref_Val=https://www.cdc.gov/vhf/crimean-congo/treatment/index.html. Accessed on June 11, 2025.
- 12. 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 11, 2025.
- 13. 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 12, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Rebetol and Ribasphere were removed from the policy; both products have been obsolete for 3 years. No criteria changes.	06/14/2023
Annual Revision	No criteria changes. Hepatitis C Virus (HCV): The note was updated to remove Viekira Pak (obsolete) and to note that the products listed within the note are examples of HCV direct-acting antivirals, but not a comprehensive list.	06/19/2024
Annual Revision	No criteria changes.	06/18/2025

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