# Clinical Policy: Ribavirin

Reference Number: CP.PHAR.141
Effective Date: 11.16.16
Last Review Date: 11.24
Line of Business: Commercial, HIM, Medicaid

Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

## Description

Ribavirin is a nucleoside analogue.

## FDA Approved Indication(s)

Ribavirin tablet is indicated for the treatment of chronic hepatitis C (CHC) virus infection in combination with Pegasys (peginterferon alfa-2a) in patients 5 years of age and older with compensated liver disease not previously treated with interferon alpha, and in adult CHC patients coinfected with HIV.

Ribavirin capsule is indicated for the treatment of CHC in combination with interferon alfa-2b (pegylated and nonpegylated) for the treatment of CHC in patients 3 years of age or older with compensated liver disease.

## Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation® that ribavirin capsule and ribavirin tablet are **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria***

**For members in **Nevada**, medical management techniques, including quantity management, beyond step therapy is not allowed.*

**A. Hepatitis C Infection** (must meet all)**:**

1. Diagnosis of hepatitis C virus (HCV) infection as evidenced by detectable serum HCV RNA levels by quantitative assay in the last 6 months;
2. Member meets prior authorization criteria for Epclusa®, Harvoni®, Mavyret®, Sovaldi®, Zepatier®, Viekira Pak®, or Vosevi® for combination use;
3. Member meets one of the following (a or b):
   a. Ribavirin tablet: Age ≥ 5 years;
   b. Ribavirin capsule: Age ≥ 3 years;
4. Dose does not exceed the following (a or b):
   a. Ribavirin tablet: 1,200 mg per day;
   b. Ribavirin capsule: 1,400 mg per day.

**Approval duration: Coincides with duration for Epclusa, Harvoni, Mavyret, Sovaldi, Zepatier, Viekira Pak, or Vosevi authorization**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

## II. Continued Therapy*

**For members in **Nevada**, medical management techniques, including quantity management, beyond step therapy is not allowed.*

**A. Hepatitis C Infection** (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed the following (a or b):
   a. Ribavirin tablet: 1,200 mg per day;
   b. Ribavirin capsule: 1,400 mg per day.

**Approval duration: Coincides with duration for Epclusa, Harvoni, Mavyret, Sovaldi, Zepatier, Viekira Pak, or Vosevi authorization**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

CHC: chronic hepatitis C
FDA: Food and Drug Administration
HCV: hepatitis C virus
HIV: human immunodeficiency virus

*Appendix B: Therapeutic Alternatives*

Not applicable

*Appendix C: Contraindications/Boxed Warnings*

- Ribavirin capsule and ribavirin tablet are contraindicated in:
  - Women who are pregnant
  - Men whose female partners are pregnant
  - Patients with hemoglobinopathies (e.g., thalassemia major, sickle-cell anemia)
  - Coadministration with didanosine
  - Patients with autoimmune hepatitis (when in combination with Pegasys)
  - When used in combination with Pegasys: Ribavirin tablet is additionally contraindicated in patients with hepatic decompensation (Child-Pugh B or C) in cirrhotic CHC patients.
- Ribavirin capsule only:
  - Patients with known hypersensitivity reactions such as Stevens-Johnson syndrome, toxic, epidermal necrolysis, and erythema multiforme to ribavirin or any component of the product
  - Creatinine clearance less than 50 mL/min
- Boxed warning(s):
  - Ribavirin tablet: risk of serious disorders and ribavirin-associated effects
  - Ribavirin capsule: embryo-fetal toxicity, hemolytic anemia, and monotherapy not recommended

*Appendix D: General Information*

- Ribavirin branded tablets and capsules are no longer commercially available.

## V. Dosage and Administration

| Drug Name | Dosing Regimen | Maximum Dose |
|---|---|---|
| Ribavirin capsules | The daily dose of ribavirin capsules is generally 800 mg to 1,400 mg PO in two divided doses. The dose should be individualized to the patient depending on baseline disease characteristics (e.g., genotype), age, response to therapy, and tolerability of the regimen. | 1,400 mg/day |
| Ribavirin tablets | The daily dose of ribavirin tablets is generally 800 mg to 1,200 mg PO in two divided doses. The dose should be individualized to the patients depending on baseline disease characteristics (e.g., genotype), age, response to therapy, and tolerability of the regimen. | 1,200 mg/day |

## VI. Product Availability

- Oral tablet: 200 mg
- Oral capsule: 200 mg

## VII. References

1. Ribavirin capsule Prescribing Information. East Windsor, NJ: Aurobindo Pharma USA, Inc.; February 2022. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=35f99f76-f2ef-4a81-91ff-285419664be3. Accessed July 30, 2024.
2. Ribavirin tablet Prescribing Information. East Windsor, NJ: Aurobindo Pharma USA, Inc.; February 2024. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=eee304d0-c2ea-44f4-97d9-92a414d31b6c. Accessed July 11, 2024.
3. American Association for the Study of Liver Diseases/ Infectious Disease Society of America (AASLD-IDSA). HCV guidance: recommendations for testing, managing, and treating hepatitis C. Last updated December 19, 2023. Available at: https://www.hcvguidelines.org/. Accessed July 29, 2024.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc. Updated periodically. Accessed July 29, 2024.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| 4Q 2020 annual review: added Mavyret and Vosevi, removed Olysio & Technivie from combination use criterion as they are no longer commercially available; expanded prescriber requirement to include a "provider who has expertise in treating HCV based on a certified training program"; Appendix E (Healthcare Provider HCV Training) added; references reviewed and updated. | 08.09.20 | 11.20 |
| 4Q 2021 annual review: no significant changes; added redirection to generic formulation; removed Daklinza criteria references as Daklinza | 08.05.21 | 11.21 |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| has been discontinued; references for HIM line of business off-label use revised from HIM.PHAR.21 to HIM.PA.154; references reviewed and updated. | | |
| 4Q 2022 annual review: Copegus, Moderiba and Rebetol oral solution removed from policy as they are no longer being manufactured (per Medispan obsolete dates and Clinical Pharmacology); added template generic redirection verbiage for generic ribavirin use; references reviewed and updated. Template changes applied to other diagnoses/indications and continued therapy section. | 08.05.22 | 11.22 |
| 4Q 2023 annual review: removed references to Ribasphere since it's no longer manufactured but retained Ribasphere Ribapak due to availability per Clinical Pharmacology; references reviewed and updated. | 08.25.23 | 11.23 |
| 4Q 2024 annual review: removed references to brand Rebetol and Ribasphere Ribapak as ribavirin brands are no longer available; removed generic redirection criterion; removed requirement for "chronic" in HCV diagnosis as ribavirin and HCV antiviral combinations are also recommended for acute HCV infections per AASLD guidance; removed specialist criterion and accompanying Appendix E; added disclaimer that medical management techniques, including quantity management, beyond step therapy are not allowed for members in NV per SB 439; references reviewed and updated. | 07.11.24 | 11.24 |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note:**
**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.