PRIOR AUTHORIZATION POLICY

POLICY: Antivirals – Ribavirin (Oral Products) Prior Authorization Policy
- ribavirin tablets (generic)
- ribavirin capsules (generic)

REVIEW DATE: 06/14/2023

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. 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 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.[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 hepatitis C virus (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 virus[13], West Nile virus[14], 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 hepatitis C virus (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 the following criteria (A and B):
   - **A)** Patient meets ONE of the following criteria (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 are Epclusa (velpatasvir/sofosbuvir tablets), Sovaldi (sofosbuvir tablets/oral pellets), Harvoni (ledipasvir/sofosbuvir tablets/oral pellets), Viekira Pak (paritaprevir/ombitasvir/ritonavir tablets + dasabuvir tablets, co-packaged), 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 COVERED

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

is(are) considered experimental, investigational or unproven 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 or the National Institutes of Health.[10,11]

REFERENCES

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HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	Policy name was changed to "Antivirals – Ribavirin (Oral Products) PA Policy"; previously, "Hepatitis C – Ribavirin PA Policy". Ribasphere tablets were removed from the policy (obsolete 3 years). **Policy Statement:** The policy statement was revised to remove reference to alfa interferon. **Automation:** Automation was updated to remove reference to "non-pegylated interferon". **Hepatitis C Virus (HCV):** Criteria were revised to approve when ribavirin is prescribed in combination with peginterferon alfa; previously, criteria approved if ribavirin was prescribed in combination with peginterferon alfa or interferon alfa. Criteria continue to approve if ribavirin is prescribed in combination with a direct-acting antiviral for hepatitis C virus. **Other Systemic Viral Infections, Excluding Coronavirus 2019 (COVID-19):** "Excluding Coronavirus 2019 (COVID-19)" was added to this criterion. **Coronavirus 2019 (COVID-19):** This condition was added to Conditions Not Covered .	06/15/2022
Annual Revision	Rebetol and Ribasphere were removed from the policy; both products have been obsolete for 3 years. No criteria changes.	06/14/2023