Clinical Policy Title:	ribavirin
Policy Number:	RxA.209
Drug(s) Applied:	ribavirin
Original Policy Date:	02/07/2020
Last Review Date:	06/10/2021
Line of Business Policy Applies to:	All lines of business

Background

Ribavirin is indicated:

- For combination therapy with interferon-alfa in patients with chronic Hepatitis C (CHC) with compensated liver disease.
- For treatment of patients with chronic Hepatitis C with compensated liver disease.

Limitation(s) of use: Patients with the following characteristics are less likely to benefit from re- treatment after failing a course of therapy: previous nonresponse, previous pegylated interferon treatment, significant bridging fibrosis or cirrhosis, and genotype 1 infection.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
ribavirin	CHC	Body Weight <75 kg: 1 g/day; Body Weight ≥75 kg: 1.2 g/day to be given in two divided doses.	Body Weight <75 kg: 1 g/day; Body Weight ≥75 kg: 1.2 g/day

* The dose should be individualized to the patient depending on baseline disease characteristics (e.g., genotype), response to therapy, and tolerability of the regimen.

Dosage Forms

- Capsule: 200 mg
- Tablet: 200 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the provisions of the pharmacy benefit administer by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

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

1. Diagnosis of chronic hepatitis C virus (HCV) infection as evidenced by detectable serum HCV RNA levels

by quantitative assay in the last 6 months;
2. Prescribed by or in consultation with a gastroenterologist, hepatologist or infectious disease specialist;
3. Prescribed in combination with other HCV drug therapy;
4. Member must meet prior authorization criteria for other HCV drug therapy used in combination with ribavirin;
5. Age 3 years of age or older (ribavirin capsule);
6. Age 5 years of age or older (ribavirin tablet);
7. Request meets one of the following (a or b)
   a. Body Weight <75 kg: 1 g/day;
   b. Body Weight ≥75 kg: 1.2 g/day.

Approval Duration
Commercial: Duration coincides with the other HCV drug therapy.
Medicaid: Duration coincides with the other HCV drug therapy

II. Continued Therapy Approval

A. Chronic Hepatitis C Infection (must meet all):
1. Member is currently receiving the medication that has been authorized by RxAdvance or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):**
   a. Body Weight <75 kg: 1 g/day;
   b. Body Weight ≥75 kg: 1.2 g/day.

Approval Duration
Commercial: Duration coincides with the other HCV drug therapy
Medicaid: Duration coincides with the other HCV drug therapy

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
CHC: Chronic Hepatitis C
HCV: Hepatitis C Virus
HIV: Human Immunodeficiency Virus
FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives
- Not applicable

APPENDIX C: Contraindications/Boxed Warnings
- Contraindication(s):
  - Women who are pregnant.
  - Men whose female partners are pregnant.
  - Patients with known hypersensitivity reactions such as Stevens-Johnson syndrome, toxic, epidermal necrolysis, and erythema multiforme to ribavirin or any component of the product.
  - Patients with autoimmune hepatitis (when in combination with pegylated interferon).
  - Patients with hemoglobinopathies (e.g., thalassemia major, sickle-cell anemia).
  - Coadministration with didanosine.
  - Patients with hepatic decompensation (Child-Pugh B or C) in cirrhotic CHC patients (when in combination with pegylated interferon.

- Boxed Warning(s):
  - Risk of serious disorders and ribavirin-associated effects.
  - Embryo-fetal toxicity.
  - Hemolytic anemia.
  - Monotherapy not recommended.

APPENDIX D: General Information

- Not Applicable

References

1. Ribavirin. In: Lexicomp Online Drug Database [database on the Internet]. Hudson, Ohio: Lexicomp, Inc.; 2020 [updated February 18, 2021]. Available at: http://online.lexi.com. Subscription required to view. Accessed March 25, 2021.
2. Ribavirin Tablet Prescribing Information. Aurobindo Pharma Limited.; November 2020. Available at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=eee304d0-c2ea-44f4-97d9-92a414d31b6c. Accessed March 25, 2021.
3. Ribavirin Capsule Prescribing Information. Aurobindo Pharma Limited.; February 2020. Available at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=35f99f76-f2ef-4a81-91ff-285419664be3. Accessed March 25, 2021.
4. Ribavirin. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed March 25, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy reviewed. 1. Formatting updated. 2. Brand drug references removed. Criteria for approval updated.	07/31/2020	09/14/2020
Policy was reviewed: 1. Dosing Information was updated. 2. Initial criteria IA. 5, 6 and 7 were updated. 3. Continued therapy criteria II.A. 7 is updated. 4. Continued therapy criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance.." 5. References were reviewed and updated.	03/25/2021	06/10/2021