RXADVANCE
2 Park Central Drive
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Clinical Policy Title:	ribavirin
Policy Number:	RxA.209
Drug(s) Applied:	ribavirin
Original Policy Date:	02/07/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Ribavirin is indicated for:

- The treatment of chronic hepatitis C (CHC) virus infection in combination with interferon alfa with compensated liver disease not previously treated
- CHC with compensated liver disease
- CHC patients coinfected with HIV

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	The daily dose of administered orally in two divided doses. The dose should be individualized to the patient depending on baseline disease characteristics (e.g., genotype), response to therapy, and tolerability of the regimen.	1,400 mg/day

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.

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;
6. Dose does not exceed 1,400 mg per 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. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy.;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1,400 mg per 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
None

References

1. Rebetol Prescribing Information. Whitehouse Station, NJ; Merck and Co; May 2019. Available at: https://www.merck.com/product/. Accessed July 31, 2020.
2. Copegus Prescribing Information. South San Francisco, CA: Genentech USA Inc, August 2015. Available at: 2020https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/021511s029lbl.pdf. Accessed July 31, .
3. Moderiba Prescribing Information. North Chicago, IL: AbbVie Inc.; December 2017. Available at: https://www.rxabbvie.com/pdf/moderiba_PI.pdf. Accessed July 31, 2020.
4. Ribasphere Prescribing Information. Warrendale, PA: Kadmon Pharmaceuticals, LLC; September 2017. Available at: http://www.kadmon.com/files/ribasphere-tablets-pi.pdf. Accessed July 31, 2020.
5. Ribavirin. In: Lexicomp Online Drug Database [database on the Internet]. Hudson, Ohio: Lexicomp, Inc.; 2020 [updated July 14, 2020]. Available at: http://online.lexi.com. Subscription required to view. Accessed July 31, 2020.
6. Ribavirin. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed July 31, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy reviewed. 1. Formatting updated. 2. Brand drug references removed. 3. Criteria for approval updated.	07/31/2020	09/14/2020