

Reference number(s)
2140-A

## SPECIALTY GUIDELINE MANAGEMENT

### RIBAVIRIN PRODUCTS (COPEGUS, MODERIBA, REBETOL, RIBASPHERE, RIBASPHERE RIBAPAK, RIBATAB, ribavirin capsules and tablets)

#### POLICY

##### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### FDA-Approved Indications

##### Copegus

Copegus is indicated for the treatment of chronic hepatitis C (CHC) virus infection in combination with Pegasys in patients 5 years of age and older with compensated liver disease not previously treated with interferon alpha, and in adult CHC patients coinfecting with HIV.

##### Moderiba

Moderiba is indicated for the treatment of chronic hepatitis C (CHC) virus infection in combination with 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 coinfecting with HIV.

##### Rebetol

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

##### Ribasphere/RibaPak

Ribasphere is indicated for the treatment of chronic hepatitis C (CHC) virus infection in combination with 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 coinfecting with HIV.

All other indications are considered experimental/investigational and are not medically necessary.

##### II. EXCLUSIONS

Exclusions to other antiviral drugs being used in combination with the requested drug apply. Refer to the SGM policy for each drug in the treatment regimen for applicable exclusions.

##### III. CRITERIA FOR APPROVAL

##### **Hepatitis C virus (HCV) infection**

Refer to the SGM of requested regimen for the specific criteria for approval and approval durations.

##### IV. REFERENCES

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1. Copegus [package insert]. South San Francisco, CA: Genentech USA, Inc.; August 2015.
2. Moderiba [package insert]. North Chicago, IL: AbbVie Inc.; December 2017.
3. Rebetol [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; May 2019.
4. Ribasphere/Ribapak [package insert]. Warrendale, PA: Kadmon Pharmaceuticals, LLC; September 2017.
5. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. <https://www.hcvguidelines.org>. Last changes made on December 10, 2019. Accessed August 01, 2020.
6. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; March 2020.
7. Viekira Pak [package insert]. North Chicago, IL: AbbVie Inc.; December 2019.
8. Zepatier [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; November 2019.
9. Epclusa [package insert]. Foster City, CA: Gilead Sciences, Inc.; July 2020.
10. Vosevi [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2017.