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 coinfected with HIV.<sup>1</sup>

## 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 coinfected with HIV.<sup>2</sup>

#### 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.<sup>3</sup>

# 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 coinfected with HIV.<sup>4</sup>

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

Ribavirin 2140-A SGM P2019

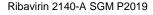
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- 2. Moderiba [package insert]. North Chicago, IL: AbbVie Inc.; December 2017.
- 3. Rebetol [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; May 2019.
- 4. Ribasphere/Ribapak [package insert]. Warrendale, PA: Kadmon Pharmaceuticals, LLC; September 2017.
- AASLD/IDSA/IAS-USA. Recommendations for testing, managing, and treating hepatitis C. https://www.hcvguidelines.org. Last changes made on December 10, 2019. Accessed December 16, 2019.
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- 7. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2017.
- 8. Viekira Pak [package insert]. North Chicago, IL: AbbVie Inc.; July 2018.
- 9. Technivie [package insert]. North Chicago, IL: AbbVie Inc.; July 2018.
- 10. Zepatier [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; June 2018.
- 11. Epclusa [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2017.
- 12. Viekira XR [package insert]. North Chicago, IL: AbbVie Inc.; July 2018.
- 13. Vosevi [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2017.



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