

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

Moderiba

Moderiba in combination with peginterferon alfa-2a is indicated for the treatment of patients 5 years of age and older with CHC virus infection who have compensated liver disease and have not been previously treated with interferon alpha.

Rebetol

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

Ribasphere/RibaPak

Ribasphere in combination with peginterferon alfa-2a is indicated for the treatment of patients 5 years of age and older with CHC virus infection who have compensated liver disease and have not been previously treated with interferon alpha.

All other indications are considered experimental/investigational and are not a covered benefit.

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

Chronic hepatitis C virus (HCV) infection

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

IV. REFERENCES

1. Copegus [package insert]. South San Francisco, CA: Genentech USA, Inc.; August 2015.
2. Moderiba [package insert]. North Chicago, IL: AbbVie Inc.; February 2015.
3. Rebetol [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; January 2016.
4. Ribasphere/Ribapak [package insert]. Warrendale, PA: Kadmon Pharmaceuticals, LLC; August 2014.

5. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. <http://www.hcvguidelines.org>. Accessed July 8, 2016. Accessed September 6, 2016.
6. Olysio [package insert]. Titusville, NJ: Janssen Products, LP; May 2016.
7. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; August 2015.
8. Viekira Pak [package insert]. North Chicago, IL: AbbVie Inc.; June 2016.
9. Technivie [package insert]. North Chicago, IL: AbbVie Inc.; June 2016.
10. Zepatier [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; January 2016.
11. Epclusa [package insert]. Foster City, CA: Gilead Sciences, Inc.; June 2016.
12. Viekira XR [package insert]. North Chicago, IL: AbbVie Inc.; July 2016.