# 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.<sup>3</sup>

#### 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.
- AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Last changes made on September 21, 2017. Accessed September 22, 2017.

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- 6. Olysio [package insert]. Titusville, NJ: Janssen Products, LP; May 2017.
- 7. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; April 2017.
- 8. Viekira Pak [package insert]. North Chicago, IL: AbbVie Inc.; March 2017.
- 9. Technivie [package insert]. North Chicago, IL: AbbVie Inc.; March 2017.
- 10. Zepatier [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; February 2017.
- 11. Epclusa [package insert]. Foster City, CA: Gilead Sciences, Inc.; August 2017.
- 12. Viekira XR [package insert]. North Chicago, IL: AbbVie Inc.; March 2017.
- 13. Vosevi [package insert]. Foster City, CA: Gilead Sciences, Inc.; July 2017.

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