Description: Ribavirin is a nucleoside analog that prevents a virus from multiplying.

Indications: 1) Ribavirin capsules in combination with interferon alfa-2b for the treatment of chronic hepatitis C in patients with compensated liver disease previously untreated with alpha-interferon or who have relapsed following alpha-interferon therapy.

Reasons for PA: ☒ Cost ☒ Potential for misuse ☒ Toxicity

Criteria for Approval: 1) Diagnosis is chronic hepatitis C with compensated liver disease and patient does not have any contraindications listed below.
2) Patient is 18 years of age or older.
3) Must be used in combination with an interferon product such as interferon alfa-2b (Intron-A), or pegylated interferon alfa-2b (Peg-Intron)
4) Viral load and genotype have been determined.
5) Patient is under the close supervision of a gastroenterologist, infectious disease specialist, or physician highly experienced in treating Hepatitis C.
6) Patient must maintain sobriety and have been sober for the last 6 months.

Reasons for Denial of Benefit: 1) Patient has any of the following contraindications
   a) Woman is pregnant or woman may become pregnant during therapy
   b) Males whose partner is pregnant and/or using < 2 appropriate forms of contraception
   c) Patient has decompensated liver disease as diagnosed by liver biopsy
   d) History of hemoglobinopathies (i.e., sickle cell anemia, thalassemia)
2) Patient does not meet criteria for approval
3) Rebetol® (ribavirin) is being prescribed alone as monotherapy.
4) Patient has history of severe kidney impairment such that Clcr is <50mL/min.

Renewal Criteria: In order to allow renewal of this medication, the patient must have an HCV RNA viral load performed at 12 and 24 weeks after treatment to determine response to therapy. Requests for renewal should be denied in patients who have not achieved HCV RNA below the limit of detection after 24 weeks of therapy or in patients who have not demonstrated a decrease in HCV RNA (response) after 12 weeks.

Benefit Approval: Approval will be for a total of 6 months in relapse patients subject to virologic test results to determine response. For previously untreated patients, approval will be for 6 months in patients with genotypes 2/3 and 12 months in patients with genotype 1, again subject to virological testing.

Quantity limits applied to Rebetol Capsules:
- In combination with Peg-Intron: #112 capsules/28 days (4wks)
- In combination with Intron-A: #140 capsules for patients £ 75kg and #168 capsules for patients > 75kg per 28 days.