

The following policy is for medication that falls under the Medicare Part D benefit only.

**Prior Authorization Group:** Chronic Hepatitis C Treatment Policy

**Drug(s):** REBETOL and RIBASPHERE (ribavirin), INFERGEN (interferon alfacon-1), PEG-INTRON (peginterferon alfa-2b), PEGASYS (peginterferon alfa-2a), COPEGUS (ribavirin)

**Covered Uses:**

- All FDA-approved indications not otherwise excluded from Part D.
- Pegylated interferon (or interferon alfa-2B) in combo with ribavirin in treatment naïve patients may be medically necessary if the following criteria are met:
  - chronic, compensated hepatitis C as documented by a positive HC antibody and quantitative HCV PCR level **AND**
  - elevated ALT levels (greater than 6 months) **OR**
  - normal ALT levels in the presence of a liver biopsy consistent with chronic hepatitis C (at least moderate inflammation and/or fibrosis).
  - no contraindications for the use of ribavirin or pegylated interferon
  - abstained from alcohol use or illegal drug use greater or equal to 6 months.
- Pegylated interferon monotherapy may be medically necessary if:
  - a member meets the appropriate criteria above and in the "other covered" section **AND**
  - member has a contraindication for use of ribavirin
- Authorization will be for 48 weeks **ALL** criteria in "other criteria" section must be met for coverage.

**Required Medical Information:** HC antibody, quantitative HCV PCR level, genotype, liver function tests, chart notes. Medical history. Liver biopsy is required for genotype 1. Liver biopsy for genotype 2 and 3 is required unless clinical rationale is provided for not performing liver biopsy. Baseline histology is a predictor of response to therapy.

**Age Restrictions:** Restricted to 18 years of age or older except when medication is FDA approved for use in pediatrics

**Prescriber Restrictions:**

Infectious disease physician, gastroenterologist, hepatologist or transplant physician

**Other Criteria:** Members with genotypes 2 and 3 who are not co-infected with HIV will be authorized for a total of 24 weeks of therapy.

1. Members with genotypes 1 and 4 who are not co-infected with HIV: obtain coverage review at 12 weeks for an additional 12 to 36-week extension if HCV RNA is undetectable or reduced by at least 2 log<sup>10</sup>

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- members who have not achieved a greater than or equal to 2 log<sub>10</sub> reduction in HCV RNA level at week 12 are unlikely to achieve SVR and further therapy is not considered medically necessary
  - those members who achieve an EVR but are still HCV RNA positive at 12 weeks should be re-tested for HCV RNA at 24 weeks
    - a. if HCV RNA is undetectable at 24 weeks, an additional 24 weeks will be authorized
    - b. members who have a detectable HCV RNA level at 24 weeks are unlikely to achieve SVR and further therapy is not considered medically necessary
2. Members with genotypes 1 and 4 who are co-infected with HIV:  
obtain coverage review at 12 weeks for an additional 12 to 36-week extension if HCV RNA is undetectable or reduced by at least 2 log<sup>10</sup>
- members with detectable HCV RNA levels and CD4 count greater or equal to 200 cells/μL will be authorized for an initial 12 weeks of therapy
    - a. members with detectable HCV RNA levels and CD4 count 100 to 199 cells/μL and HIV RNA titer less than 5000 copies/mL will be authorized for an initial 12 weeks of therapy
    - b. members who have not achieved a greater than or equal to 2 log<sub>10</sub> reduction in HCV RNA level at week 12 are unlikely to achieve SVR and further therapy is not considered medically necessary
    - c. those members who achieve an EVR but are still HCV RNA positive at 12 weeks should be re-tested for HCV RNA at 24 weeks
      - a. if HCV RNA is undetectable at 24 weeks, an additional 24 weeks will be authorized
    - d. members who have a detectable HCV RNA level at 24 weeks are unlikely to achieve SVR and further therapy is not considered medically necessary
3. Members with genotypes 2 and 3 who are co-infected with HIV:
- members with detectable HCV RNA levels and CD4 count greater or equal to 200 cells/μL will be authorized for 48 weeks of therapy
  - members with detectable HCV RNA levels and CD4 count 100 to 199 cells/μL and HIV RNA titer less than 5000 copies/mL will be authorized for 48 weeks of therapy
4. Members with all genotypes who are not co-infected with HIV and have contraindication for use of ribavirin:
- obtain coverage review at 12 weeks for an additional 12 to 36-week extension if HCV RNA is undetectable or reduced by at least 2 log<sub>10</sub>
  - those members who achieve an EVR but are still HCV RNA positive at 12 weeks should be re-tested for HCV RNA at 24 weeks
    - 3) if HCV RNA is undetectable at 24 weeks, an additional 24 weeks will be authorized
    - 4) members who have a detectable HCV RNA level at 24 weeks are unlikely to achieve SVR and further therapy is not considered medically necessary

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**Exclusion Criteria:** Coverage for pegylated interferon and ribavirin therapy is not considered medically necessary for the following members:

- member with genotype 1, 2, 3, or 4 co-infected with HIV with undetectable HCV RNA levels or CD4 count less than 100 cells/ $\mu$ L or HIV RNA titer less than 5000 copies/mL and CD4 count less than 100 cells/ $\mu$ L.
- contraindications for the use of ribavirin, including pregnancy, renal failure, hemoglobinopathies
- contraindications for the use of pegylated interferon, including autoimmune hepatitis, decompensated liver disease (i.e. hepatic encephalopathy, ascites, portal hypertension, jaundice, etc.,
- heart, lung, or kidney transplant recipients,
- who have not responded or have relapsed following a course of pegylated interferon,
- continuation of therapy beyond the timeframes allowed above,
- members who have relapsed, defined as previously responding to therapy as evidenced by greater than or equal to a 2 log decrease in HCV RNA or undetectable HCV RNA, following therapy with interferon and ribavirin,
- members with recurrent hepatitis C following liver transplant,
- members with acute hepatitis C,
- doses exceeding:
  - pegylated interferon alpha-2b (Peg-Intron): 1.5 mcg/kg/week
  - pegylated interferon alpha-2a (Pegasys): 180 mcg/week
  - FDA approved dosing.
- The use of any interferon for maintenance therapy is considered investigational,
- Monitoring of HCV RNA levels is limited to the monitoring of treatment response.
- The use of interferon-alfacon-1 is considered investigational for members who have relapsed or are considered non-responders or inadequate responders to prior interferon therapy.

**Coverage Duration:** Initial approval 12-48 weeks duration depending on genotype. Total coverage duration 24-48 weeks.