

HealthAlliance**MEDICARE**

PURPOSE OF THE POLICY

To define criteria for coverage of interferon and interferon/ribavirin in the treatment of hepatitis C for new starts only.

STATEMENT OF THE POLICY

Health Alliance will not reimburse for interferon and interferon/ribavirin combination therapy unless the member meets the prior authorization criteria.

PROCEDURES

1. Clinical Pharmacist Review Criteria for initial approval

- 1.1 Positive HCV RNA, AND
- 1.3 Genotype known, AND
- 1.4 Liver biopsy for genotype 1, 4 or 6 showing chronic hepatitis with fibrosis (stage 1 or greater) AND
- 1.5 No prior treatment OR
- 1.6 Retreatment with peginterferon plus ribavirin for non-responders or relapsers who have significant fibrosis or cirrhosis and who have undergone previous regimens of treatment using interferon monotherapy or non-pegylated interferon.

2. Continuation of therapy

- 2.1 Treatment with interferon/ribavirin combination is limited to 24 weeks in patients with genotype 2 or 3
- 2.2 Patients are eligible for a total of 48 weeks of combination therapy with interferon/ribavirin if they meet the following criteria:
 - Genotype 1, 4 or 6
 - Early virological response (a fall in HCV RNA level to undetectable or by at least 2 log₁₀ units at 12 weeks). Patients who are still HCV RNA positive at 12 weeks should be retested at 24 weeks and coverage ends if still positive.

3. Non-coverage situations

- 3.1 Women who are pregnant or are unwilling or unable to comply with adequate contraception and the male partners of women who are pregnant, OR
- 3.2 Patients with less than six (6) months abstinence from alcohol or illicit drug use, OR
- 3.3 Patients with decompensated cirrhosis, OR
- 3.4 Ribavirin for patients with anemia (HGB concentration less than 12Gm/dl in women, less than 13Gm/dl in men), OR
- 3.5 Patients with uncontrolled psychiatric disorders (including major depression), cytopenias, uncontrolled hyperthyroidism, severe concurrent disease, autoimmune-type disease or history of heart, lung, or renal transplantation.

- 3.6 Patients with renal failure – Ribavirin will not be covered, dose of interferon will be reduced by 50%).
- 3.7 Non-responders or relapsers who have undergone previous treatment using pegylated interferon and ribavirin.

4. ICD-9 CM Diagnosis Code

070.54 - Type C Chronic

5 Covered Products

- 5.1 PEG-Intron® & Rebetol®
- 5.2 Pegasys® & Copegus®

6 References

- 6.1 Battaglia AM, Hagmayer KO. Combination therapy with interferon and ribavirin in the treatment of chronic hepatitis C infection. *Ann Pharmacother* 2000; 24:487-94.
- 6.2 McHutchinson JG, Gordon SC, et al. Interferon alfa-2b alone or in combination with ribavirin as initial treatment for chronic hepatitis C. *NEJM* 1998; 339:1485-1492.
- 6.3 NIH Consensus Development Conference Statement on the Management of Hepatitis C – 7.15.97.
- 6.4 Poyntart T, Marcellin P, et al. Randomized trial of interferon alfa-2b plus ribavirin for 48 weeks or for 24 weeks versus interferon alfa-2b plus placebo for 48 weeks for treatment of chronic infection with hepatitis C virus. *Lancet* 1998; 352:1426-1432.
- 6.5 Lauer GM, Walker BD. Hepatitis C virus infection. *NEJM* 2001:41-51
- 6.6 Management of Hepatitis C: 2002. *Hepatology* November, 2002, part 2, 36(5).
- 6.7 Strader D, Wright T, Thomas D, Seeff L, et al. Diagnosis, Management and Treatment of Hepatitis C, AASLD Practice Guidelines, April 2004