

# 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 Approved for FDA approved indications.
- 1.2 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 log<sub>10</sub> 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

- 3.3 Patients with decompensated cirrhosis, OR
- 3.4 Non-responders or relapsers who have undergone previous treatment using pegylated interferon and ribavirin.

### 4. References

- 4.1 Battaglia AM, Hagmayer KO. Combination therapy with interferon and ribavirin in the treatment of chronic hepatitis C infection. *Ann Pharmacother* 2000; 24:487-94.
- 4.2 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.

- 4.3 NIH Consensus Development Conference Statement on the Management of Hepatitis C – 7.15.97.
- 4.4 Poynart 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.
- 4.5 Lauer GM, Walker BD. Hepatitis C virus infection. *NEJM* 2001:41-51
- 4.6 Management of Hepatitis C: 2002. *Hepatology* November, 2002, part 2, 36(5).
- 4.7 Strader D, Wright T, Thomas D, Seeff L, et al. Diagnosis, Management and Treatment of Hepatitis C, AASLD Practice Guidelines, April 2004