

PURPOSE OF THE POLICY

To define criteria for coverage of Sylatron in the treatment of Hepatitis C, for new starts only.

STATEMENT OF THE POLICY

Health Alliance will provide coverage for Sylatron therapy for Hepatitis C with the below prior authorization criteria and B v D decisions when Sylatron is used for malignant melanoma.

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
- 1.5 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.
- 1.7 Prior authorization will be for Medicare Part B or Part D decisions when Sylatron is being used for the treatment of Malignant Melanoma

2. Continuation of therapy

- 2.1 Interferon alfa-naïve patients with peg-interferon/ribavirin treatment 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 peg-interferon/ribavirin if they meet the following criteria:
 - Genotype 1, 4 or 6
 - Genotype 2 or 3 AND not interferon alfa-naïve
 - Early virological response (a fall in HCV RNA level to undetectable or by at least 2 log 10 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.
- 2.3 Chronic Hepatitis C interferon alfa-naïve patients with compensated liver disease are eligible for 1 year monotherapy treatment at 1mcg/kg/wk subcutaneous

3. Non-coverage situations

- 3.1 Patients with decompensated cirrhosis, OR
- 3.2 Non-responders or relapsers who have undergone previous treatment using pegylated interferon and ribavirin.
- 3.3 Pregnant or partner is pregnant
- 3.4 Anaphylaxis history with peginterferon alpha-2B or interferon alpha-2B
- 3.5 Renal impairment with creatinine clearance less than 50ml/min when in combination with ribavirin

HISTORY

9.1.2011-THowerton-policy created for Part D