

Neighborhood Health Plan of Rhode Island
Prior Authorization Guideline
Pegasys® (pegylated interferon alfa-2a)

Description: Pegasys is a recombinant alfa-2a interferon branched to a polyethylene glycol (PEG) molecule which exerts antiviral, antiproliferative, and immunomodulating effects. This molecule delays clearance of the interferon producing a long-acting product which can be administered on a once weekly schedule.

Indications: Treatment of chronic Hepatitis C alone or in combination with oral ribavirin tablets (Copegus™) in adult patients with compensated liver disease who have not previously been treated with interferon alfa.

Reasons for PA: Cost Potential for fraud or 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, not previously treated with pegylated interferon alfa therapy.
3. Viral load and genotype have been determined.
4. Patient is under the close supervision of a gastroenterologist, infectious disease specialist, or physician highly experienced in treating Hepatitis C.
5. Maintenance of sobriety for the last 6 months and going forward.

Reasons for Denial of Benefit:

1. Patient has any of the following **contraindications:**
 - a) Hypersensitivity to Pegasys or any component of the product.
 - b) Patient has decompensated liver disease as diagnosed by liver biopsy or autoimmune hepatitis
 - c) Contains benzyl alcohol; use contraindicated in infants & neonates
2. **Combination with oral ribavirin is contraindicated in:** pregnant women, males whose female partner is pregnant and using <2 forms of contraception, and in hemoglobinopathies (sickle cell anemia, thalassemia major).
3. Patient does not meet criteria for approval.

Renewal Criteria: In order to allow renewal of this medication, the patient must have an HCV RNA viral load performed 12 and 24 weeks after treatment initiation to determine response. Request should be denied in patients whose HCV RNA level remains detectable or elevated after 12-24 weeks of Pegasys® therapy or in patients who have not demonstrated a decrease in HCV RNA (response defined as a 2-log decrease in some studies) after 12-24 weeks.

Benefit Approval: Approval for a total of 1 year (48 wks) in patients with genotypes 1, 4 and 6 months in patients with genotypes 2, 3 who respond as demonstrated by PCR tests of HCV RNA levels. Safety & efficacy beyond 48 wks has not been established. National guidelines currently recommend against retreatment using pegylated interferon products combined with ribavirin.

References:

1. Hoffman-La Roche Pegasys Package Insert. Nutley, NJ. December 2003.
2. Satoor SS, Raufman JP. Treatment of Hepatitis C. *Clin Cornerstone* 2001;3:37-46.
3. Fried MW, Shiffman ML, Reddy KR, et al. Peginterferon alfa-2a plus ribavirin for chronic Hepatitis C virus infection. *NEJM* 2002. 347;(13):975-82.
4. Lee S, Heathcote E, Reddy K, et al. Prognostic factors and early predictability of sustained viral response with peginterferon alfa-2a. *J Hepatol* 2002. 37;(4):500.
5. Strader D, Wright T, Thomas D, Seeff L. Diagnosis, management, and treatment of Hepatitis C - AASLD Practice Guideline. *Hepatology* 2004; 39: 1147-71.