Blue Cross Blue Shield of Vermont and The Vermont Health Plan
Pegasys® (pegylated interferon alfa-2a)
Prior Approval Guidelines

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 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 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. Patient must maintain sobriety & have been sober within last 6 months.

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. Patient does not meet criteria for approval.
3. Combination with oral ribavirin is contraindicated in: pregnant women, males whose female partner is pregnant and using <2 forms of contraception, and in pts with hemoglobinopathies (sickle cell anemia, thalassemia major)
4. Retreatment after a previously failed 12 week trial (Non-responders)
5. Patient that relapse after completed therapy 24 week or 48 week successful therapy

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. Requests 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 2-log decrease in HCV RNA (response) viral load (titer) from baseline 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. Retreatment of patients who have relapsed following therapy with Pegasys® has not been studied.

References: