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

Description: Peg-Intron is a recombinant alpha 2-b interferon conjugated to a polyethylene glycol molecule which exerts antiviral 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:
1. Treatment of chronic hepatitis C in patients with compensated liver disease who have not previously been treated with interferon alpha.
2. Patients is 18 years of age or older.
3. Alone or in combination with Rebetol® [ribavirin] capsules

Reasons for Prior Authorization: □ Cost □ Potential for misuse

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 w/in last 6 months.

Reasons for Denial of Benefit:
1. Patient has any of the following contraindications:
   a) Hypersensitivity to Peg-Intron or any component of the product.
   b) Patient has decompensated liver disease as diagnosed by liver biopsy or autoimmune hepatitis.
2. Combination with Rebetol (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 to determine response. Request should be denied in patients whose HCV RNA level remains elevated after 24 weeks of Peg-Intron® therapy or in patients who have not demonstrated a decrease in HCV RNA (response) after 12 weeks.

Benefit Approval:
Approval for a total of 1 year (48 wks) in patients with genotype 1 and 6 months in patients with genotype 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 Peg-Intron has not been studied.

References: