



## Prior Authorization Approval Criteria

### PEG-Intron, Pegasys

#### (peginterferon alfa 2b, peginterferon alfa 2a)

- Generic name:** peginterferon alfa-2b, peginterferon alfa-2a
- Brand name:** PEG-Intron, Pegasys
- Medication class:** interferon/antiviral
- FDA-approved uses:** For use alone or in combination with ribavirin for the treatment of chronic hepatitis C.  
Treatment of chronic hepatitis C in patients coinfecting with hep C and HIV whose HIV is clinically stable.  
Pegasys only: Treatment of patients with HBeAg positive and HBeAg negative chronic hepatitis B.
- Usual doses:**
- Monotherapy Hep C:
- PegIntron: 1.0 ug/kg/week for one year
  - Pegasys: 180 mcg/week (Hep C alone and Hep C with HIV)
- Monotherapy Hep B:
- Pegasys: 180 mcg/ week
- Combination therapy (with ribavirin) Hep C:
- PegIntron: 1.5 ug/kg/week
  - Pegasys: 180 mcg/week (Hep C alone and Hep C with HIV)
- Duration of therapy:** Hep C:
- Monotherapy: one year for all Genotypes.
  - Combination therapy: genotype 1 and 4 - 48 weeks; genotypes (2 and 3) - 24 weeks.
  - Hep C with HIV: all genotypes - 48 weeks
  - Hep B: 48 weeks

**Criteria for use:** *(bullet points below are all inclusive unless otherwise noted)*

Peginterferon alfa-2b and 2a in combination with ribavirin:

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Clinically documented chronic hepatitis C with detectable HCV RNA levels > 50IU/ml
- No previous use with interferon alpha.
- Age 3 and older.
- Liver biopsy (unless contraindicated) shows some fibrosis and inflammatory necrosis.
- If patient has HIV they must be clinically stable.
- If approved, Peg Intron must be used. Pegasys will only be approved if patient is intolerant of Peg Intron.

**Criteria for continuation of therapy:**

Additional 24 weeks:

- Patient must have HCV genotype 1 or 4.
- After 24 weeks the patient has undetectable HCV RNA levels.
- Must provide the patients most recent CBC including hct and hgb.

**Criteria for use:**

Peginterferon alfa-2b and 2a as monotherapy for up to 48 weeks:

- Patients meet the above criteria with the exception of having contraindications to ribavirin (see below).

**Criteria for use:**

Peginterferon alfa 2a (Pegasys) for chronic hepatitis B:

- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.
- Clinically documented HBeAg positive or HBeAg negative chronic hepatitis B
- Compensated liver disease
- Evidence of viral replication
- Evidence of liver inflammation
- Four agents licensed for treatment of chronic hep B: interferon alfa, lamivudine, entecavir, and adefovir dipivoxil.

**Contraindications:**

- Hypersensitivity to peginterferon or any other component of the product.
- Autoimmune hepatitis.
- Decompensated liver disease.

**Not approved if:**

- Patient is not naïve to interferon alpha.
- Patient has any contraindications to the use of peginterferon.

**Ribavirin contraindications;**

- Women who are pregnant or in men whose female partners cannot practice birth control.
- Patients with a history of hypersensitivity to ribavirin or any component of the capsule.
- Patients with autoimmune hepatitis.
- Patients with hemoglobinopathies (eg. thalassemia major, sickle-cell anemia).

**Suggested guidelines for dose modification and discontinuation of interferon/ribavirin for hematologic toxicity:**

Laboratory values	Peginterferon	Ribavirin
Hgb* <10.0 g/dl <8.5 g/dl	----- Permanently discontinue	Decrease by 200 mg/day Permanently discontinue
WBC <1.5 x10/L <1.0 x10/L	Reduce dose by 50% Permanently discontinue	----- Permanently discontinue
Neutrophil <0.75 x10/L <0.5 x10/L	Reduce dose by 50% Permanently discontinue	----- Permanently discontinue
Platelets <80 x10/L <50 x10/L	Reduce dose by 50% Permanently discontinue	----- Permanently discontinue

*\* For patients with a history of stable cardiac disease receiving peginterferon in combination with ribavirin, the peginterferon dose should be reduced by half and the ribavirin dose by 200 mg/day if a >2 g/dL decrease in hemoglobin is observed during any 4 week period. Both peginterferon and ribavirin should be permanently discontinued if patients have hemoglobin levels < 12 g/dL after this ribavirin dose reduction.*

78% of patients infected with HCV genotype non-1 achieved an SVR with treatment of 180 ug of Pegasys in combination with 800 mg of ribavirin for 24 weeks; treatment with a higher ribavirin dosage and/or for a longer duration resulted in a similar percentage of SVR.

Patients infected with HCV genotype-1 achieved the highest SVR of 51% when treated with 180 ug of Pegasys plus 1000 mg to 1200 mg of ribavirin for 48 weeks.

P&T Approval: \_\_\_\_\_ Date: \_\_\_\_\_

Adopted: 11/17/04  
Revised: 12/09/09