

PEGASYS® (peginterferon alfa-2a)

GPI CODING:

1235306005****

DESCRIPTION:

Pegasys is a pegylated interferon indicated for the treatment of adults with chronic hepatitis C virus (HCV) infection who have compensated liver disease and have not been previously treated with interferon alpha. Pegasys is also indicated for the treatment of adult patients with hepatitis B e antigen (HBeAg)-positive and HBeAg-negative chronic hepatitis B infection who have compensated liver disease and evidence of viral replication and liver inflammation.

APPROVAL DURATION:

Hepatitis C

Genotype 1, in combination with ribavirin: initial, 12 weeks; total, 48 weeks

Genotype 2 or 3: 24 weeks

All genotypes, as monotherapy: initial, 12 weeks; total, 48 weeks

Hepatitis B: 48 weeks

CRITERIA FOR PEGASYS

I. Hepatitis C Genotype 1

A. Pegasys, in combination with ribavirin, may be approved in patients with confirmed HCV with compensated liver disease for up to an initial 12 weeks of therapy when all of the following criteria have been met:

1. Detectable HCV RNA; **AND**
2. Liver biopsy (unless contraindicated) shows some fibrosis and inflammation or necrosis; **AND**
3. When one of the following criteria has been met:
 - i. Treatment naïve patients; **OR**
 - ii. Patients with significant fibrosis or cirrhosis who received previous treatment using non-pegylated interferon monotherapy or in combination with ribavirin who demonstrate no response or have relapsed; **OR**
 - iii. Patient has not received previous treatment with pegylated interferon in combination with ribavirin.

B. Pegasys, in combination with ribavirin, may be approved for patients with HCV genotype 1 currently receiving therapy who require an additional 36 weeks of treatment (to complete a total of 48 weeks) of therapy when the following criteria has been met:

1. A documented early viral response (EVR) at week 12 of initial therapy.
 - i. An EVR is defined as a decrease in HCV RNA $> 2 \log_{10}$ (i.e. from 1,200,000 to 12,000) from baseline; **OR**
 - ii. A decrease in HCV RNA to undetectable levels.

II. Hepatitis C Genotype 2 or 3

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A. Pegasys, in combination with ribavirin, may be approved in patients with confirmed HCV for a course of treatment not to exceed 24 weeks in duration for patients with all the following conditions:

1. Detectable HCV RNA, **AND**
2. Compensated liver disease, **AND**
3. When one of the following criteria has been met:
 - i. Treatment naïve patients; **OR**
 - ii. Patients with significant fibrosis or cirrhosis who received previous treatment using non-pegylated interferon monotherapy or in combination with ribavirin who demonstrate no response or have relapsed.

III. Hepatitis C Antiviral Therapy in Patients with a Contraindication to Ribavirin

A. Pegasys monotherapy may be approved in patients with a contraindication to ribavirin and confirmed HCV with compensated liver disease for up to 48 weeks when the following criteria have been met:

1. Any genotype; **AND**
2. Detectable HCV RNA; **AND**
3. If liver biopsy is performed, fibrosis and inflammation or necrosis are present; **AND**
4. When one of the following criteria have been met:
 - i. Patient has not received previous treatment with pegylated interferon monotherapy **OR**
 - ii. Patient has received previous non-pegylated interferon monotherapy with no response or relapse has occurred.

IV. Chronic Hepatitis B Infection

A. Patient must meet all of the following:

1. Patient has a diagnosis of Chronic Hepatitis B, **AND**
2. HBeAg either positive or negative, **AND**
3. Hepatitis B DNA > 10⁵ copies/ml, **AND**
4. ALT at least 2x upper limit of normal (ULN).

B. Pegasys is approved only for use in adults.

C. Pegasys will NOT be approved for the treatment of chronic hepatitis B in any of the following conditions:

1. In individuals whose ALT < 2x ULN **OR**
2. In individuals with cirrhosis or clinically decompensated liver disease **OR**
3. In individuals with inactive HBsAg carrier state **OR**
4. In pregnant women or those who may become pregnant **OR**
5. Combination therapy, either with oral medication (Baraclude, Epivir HB, Hepsera, Tyzeka), injectable medication, or a combination of oral and injectable medication.