Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

PEGINTRON® (peginterferon alfa-2b)

GPI CODING:

123530601064**

DESCRIPTION:

PegIntron is a pegylated interferon indicated for the treatment of chronic hepatitis C infection, in combination with ribavirin, in patients three years of age and older with compensated liver disease. PegIntron is also indicated as monotherapy for chronic hepatitis C patients who are intolerant to ribavirin and who are at least 18 years of age.

APPROVAL DURATION:

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

CRITERIA FOR PEGINTRON

I. Hepatitis C Genotype 1

A. PegIntron, 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. PegIntron, 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

A. PegIntron, 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. PegIntron 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.