SECTION 1: Hepatitis C – Pegintron

Prior-Approval Requirements

Age  18 years of age or older

Diagnosis

Patient must have the following:

1. Chronic hepatitis C

AND ALL of the following:

a. Detectable viral load in the serum
b. Compensated liver disease
c. NOT previously treated
d. Significant intolerance or contraindication to ribavirin or other antiviral agents
e. A viral load will be drawn at treatment week 24

Prior - Approval Limits

Duration  7 months

Prior – Approval Renewal Requirements

Diagnosis

Patient must have an UNDECTABLE hepatitis C viral load after initial 24 weeks of therapy

Prior – Approval Renewal Limits

Duration  5 months
PEGINTRON
(peginterferon alfa-2b)

PEGINTRON (peginterferon alfa-2b) with RIBAVIRIN
(Copegus, Moderiba, Rebetol, Ribapak, Ribasphere, Ribatabs, ribavirin - all strengths)

Pre - PA Allowance
None

Prior-Approval Requirements

Age 3 years of age or older

Diagnosis

   Patient must have the following:

   1. Chronic hepatitis C

   AND ALL of the following:
   a. Detectable viral load in the serum
   b. Compensated liver disease
   c. Viral genotype must be provided and if genotype 1 must NOT be an appropriate candidate for treatment with a protease inhibitor
   d. NOT diagnosed with renal failure if age 3 to 17
   e. Neither the patient nor the partner of the patient is pregnant
   f. Will be instructed to practice effective contraception during therapy and for 6 months after stopping ribavirin therapy if either the patient or their partner are of child bearing age
   g. Viral load will be drawn at treatment week 24 if not coinfected with HIV

Prior - Approval Limits

Duration 7 months (if not HIV infected)
12 months (if HIV infected)

Prior – Approval Renewal Requirements

Diagnoses

   Patient must have ALL of the following:

   1. UNDETECTABLE hepatitis C viral load after initial 24 weeks of therapy
   2. Genotype 1, 4, 5 or 6

   AND NONE of the following:

   1. HIV infection and already treated for 12 months
   2. History of null or partial response to previous (non-protease inhibitor therapy)
   3. Presence of cirrhosis

Pegintron FEP Clinical Criteria
PEGINTRON
(peginterferon alfa-2b)

Prior - Approval Renewal Limits
Duration
5 months (if age 3 to 17)
12 months (if age 18 or older)

SECTION 3: Pegintron, Ribavirin, & Sovaldi - Hepatitis C

PEGINTRON (peginterferon alfa-2b) with SOVALDI AND RIBAVIRIN
(Copegus, Moderiba, Rebetol, Ribapak, Ribasphere, Ribatabs, ribavirin - all strengths)

Pre - PA Allowance
None

Prior-Approval Requirements
Age
18 years of age or older

Diagnosis

Patient must have the following:

1. Chronic Hepatitis C

AND ALL of the following:
   a. Viral genotype 1 or 4
   b. Sovaldi will NOT be used as monotherapy
   c. Patient does NOT have hepatocellular carcinoma awaiting transplant (these patients should be treated with Sovaldi and ribavirin without interferon)
   d. Absence of renal impairment
      a. eGFR must be > 30mL/min/1.73m²
      e. Absence of end stage renal disease (ESRD)
   f. Patient does NOT have decompensated cirrhosis
   g. Patient has NOT had a liver transplant
   h. Absence of significant or unstable cardiac disease
   i. Neither the patient nor the partner of the patient is pregnant
   j. If patient or their partner are of child bearing age, the patient has been or will be instructed to practice effective contraception during therapy and for 6 months after stopping ribavirin therapy.

Prior - Approval Limits
Duration
Sovaldi 12 weeks (84 tablets for 84 days)
PegIntron 12 weeks / Ribavirin 12 weeks

Pegintron FEP Clinical Criteria
Prior – Approval Renewal Requirements
None

Section 4: Peginteron, Ribavirin, & Olysio – Hepatitis C

Peginteron (peginterferon alfa-2b) with Olysio and Ribavirin (Copegus, Moderiba, Rebetol, Ribapak, Ribasphere, Ribatabs, ribavirin - all strengths)

Pre-PA Allowance
None

Prior-Approval Requirements

Age
18 years of age or older

Diagnosis

Patient must have the following:

Chronic Hepatitis C

**AND ALL** of the following:
1. Viral genotype 1 and if subtype 1a, the patient does NOT have NS3 Q80k polymorphism
2. Detectable viral load in the serum
3. A viral load will be drawn at treatment weeks 4, 12, and 24
4. Olysio will **NOT** be used as monotherapy
5. Olysio dose will **NOT** be reduced or interrupted
6. Compensated liver disease (i.e. stable liver problems; a diseased liver that is functional)
7. Patient has **NOT** been previously treated with a triple therapy regimen containing a hepatitis C virus protease inhibitor (such as: Incivek, Victrelis)
8. Patient has **NOT** had a liver transplant
9. Neither the patient nor the partner of the patient is pregnant
10. If patient or their partner are of child bearing age, the patient has been or will be instructed to practice effective contraception during therapy and for 6 months after stopping ribavirin therapy
11. Must be prescribed by a board-certified gastroenterologist, hepatologist,
PEGINTRON
(peginterferon alfa-2b)

oncologist, or infectious disease specialist
12. NO history of alcohol and/or substance abuse in the past 6 months

Prior - Approval Limits
Duration

Previously untreated patient (treatment naïve) or relapser
12 weeks for Olysio
24 weeks for PegIntron, and ribavirin

Previous non-responder (partial or null response)
12 weeks for Olysio
28 weeks for PegIntron, and ribavirin

Prior – Approval Renewal Requirements

Diagnosis

Patient must have ALL of the following:
1. Completed 12 weeks of Olysio
2. UNDETECTABLE hepatitis C viral load at treatment weeks 12 & 24
3. Patient had prior interferon-based therapy (dual therapy without a protease inhibitor) and relapsed or had a non-response (partial or null)

Prior - Approval Renewal Limits
Duration

Previously untreated patient (treatment naïve) or a relapser
NO additional authorization for Olysio, PegIntron, and ribavirin

Previous non-responder (partial or null response)
20 weeks for PegIntron, and ribavirin