Peginterferon Prior Authorization Criteria

Program may be implemented with the following options
option 1) Prior authorization through preferred product
option 2) Step therapy through preferred product
option 3) Prior authorization for all products (no product preference)

For Blue Cross and Blue Shield of Illinois, Option 1 (prior authorization through preferred peginterferon product Pegasys) will apply.

### FDA APPROVED INDICATIONS AND DOSAGE\(^1,2\)

<table>
<thead>
<tr>
<th>Available Products</th>
<th>FDA Indication(s)</th>
<th>Dosage and Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pegasys</strong></td>
<td>• Chronic, Active Hepatitis B (≥18 years)</td>
<td>• 180 mcg sc once weekly for 48 weeks</td>
</tr>
<tr>
<td>(peginterferon alfa-2a) subcutaneous injection</td>
<td>• Chronic Hepatitis C (≥18 years), interferon-alpha naïve</td>
<td>• 180 mcg sc once weekly and ribavirin 800 mg po daily given in two divided doses for a total of 48 weeks, regardless of genotype</td>
</tr>
<tr>
<td></td>
<td>• Hepatitis C + HIV co-infection (≥18 years)</td>
<td>• 180 mcg sc once weekly</td>
</tr>
<tr>
<td></td>
<td>• Chronic Hepatitis C (≥18 years), interferon-alpha naïve in combination with ribavirin</td>
<td>• 180 mcg sc once weekly and ribavirin 800-1200 mg (based on weight and genotype) po daily given in two divided doses for the total of 24 weeks (genotypes 2, 3) or 48 weeks (genotypes 1, 4)</td>
</tr>
<tr>
<td></td>
<td>• Chronic Hepatitis C + HIV co-infection (≥18 years) in combination with ribavirin</td>
<td>• 1 mcg/kg/week sc for 1 year administered on the same day of the week</td>
</tr>
<tr>
<td><strong>PegIntron</strong></td>
<td>• Chronic Hepatitis C (≥18 years), interferon-alpha naïve or prior treatment failure</td>
<td>• 60 mcg/m(^2)/week sc in combination with 15 mg/kg/day of ribavirin orally in two divided doses for 24 weeks (genotypes 2, 3) or 48 weeks (genotype 1)</td>
</tr>
<tr>
<td>(peginterferon alfa-2b) subcutaneous injection</td>
<td>• Chronic Hepatitis C in patients (age 3-17 years), interferon-alpha naïve or prior treatment failure, in combination with ribavirin</td>
<td>• 1.5 mcg/kg/week sc in combination with 800 to 1400 mg of ribavirin (based on body weight) for 24 weeks (genotypes 2, 3) or 48 weeks (genotype 1)</td>
</tr>
</tbody>
</table>

sc – subcutaneously; po – orally

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CLINICAL RATIONALE
Peginterferon for the Treatment of Hepatitis C
Patients who react positively to enzyme immunoassay for antibody to hepatitis C virus (HCV) or HCV RNA and have compensated liver disease are potential candidates for peginterferon therapy.\(^3\) Proper duration of treatment is 12 continuous months for infection with HCV genotype 1, 4, 5, or 6 if there is a response to therapy at 12 weeks and six continuous months for genotype 2 and 3 which may be extended to 12 continuous months if there is evidence of cirrhosis, high viral load, or delayed response (response at 24 weeks versus 12 weeks)\(^4,5\). There is evidence that patients considered slow responders (positive HCV RNA after 12 weeks of treatment but HCV RNA negative after 24 weeks) may benefit from a 72 week course of therapy.\(^6,7\)

Comparative Clinical Trials of Peginterferon
Guidelines from the National Institutes of Health (NIH), National Institute for Health and Clinical Excellence (NICE), American Association for the Study of Liver Diseases (AASLD), and American Gastroenterological Association (AGA) also support a conclusion of similar efficacy between peginterferon products.\(^8-10\); however, all of the guidelines were written before the publication of several head-to-head, non-industry sponsored, investigator initiated, single center studies that found peginterferon \(\alpha\)-2a to achieve higher sustained viral response rates (SVR) when compared to peginterferon \(\alpha\)-2b.\(^12,13\)

- Two independent, investigator-initiated, single-center, open-label, randomized trial compared the efficacy of peginterferon alfa-2a and peginterferon alfa-2b at standard doses and durations according to manufacture prescribing information. Both regimens were in combination with the ribavirin. The primary end point of both trials was SVR. Significantly more patients in the peginterferon alfa-2a group than in the peginterferon alfa-2b group achieved an SVR in one trial (110/160 [68.8%] vs 87/160 [54.4%]; \(p=0.008\))\(^12\). SVR was significantly higher in the peginterferon alfa-2a than in the peginterferon alfa-2b patients (66% vs 54%, respectively \(p=0.02\)) and 48% vs 32% in 222 HCV-1 and 4 patients (\(p=0.04\)), and 96% vs 82%, respectively, in the HCV 2 patients (\(p=0.01\))\(^13\) in another trial.
- A systematic review of head-to-head trials between the two PEG-IFN products assessed the benefits and harms of the 2 treatments (12 trials, n=5,008).\(^11\)
  - Peginterferon alfa-2a significantly increased the number of patients who achieved a SVR versus peginterferon alfa-2b (8 trials: 47% vs 41%; risk ratio 1.11, 95% CI 1.04-1.19; \(p=0.004\)).
  - No significant differences in adverse effects were found a between the two PEG-IFN products.

AASLD guidelines: Retreatment of Persons Who Failed to Respond to Previous Treatment for Chronic Hepatitis C\(^14\):
- Retreatment with peginterferon and ribavirin in patients who did not achieve an SVR after a prior full course of peginterferon and ribavirin is not recommended, even if a different type of peginterferon is administered.
- Retreatment with peginterferon and ribavirin can be considered for non-responders or relapers who have previously been treated with non-peginterferon with or without ribavirin, or with peginterferon monotherapy, particularly if they have bridging fibrosis or cirrhosis.
- Maintenance therapy is not recommended for patients with bridging fibrosis or cirrhosis who have failed a prior course of peginterferon and ribavirin.

Peginterferon for the Treatment of Hepatitis B
The diagnosis of hepatitis B virus (HBV) is based on the presence of serological markers in the blood; hepatitis B viral DNA (HBV DNA), hepatitis B surface antigen (HBsAg) or hepatitis B ‘e’
antigen (HBeAg).\textsuperscript{15} The AASLD 2009 guideline\textsuperscript{16} for the treatment of hepatitis B virus recommends initiation of treatment with any of the seven approved antiviral medications but peginterferon, tenofovir, or entecavir are preferred. Advantages of peginterferon include a finite duration of treatment, a more durable response, and lack of resistant mutants. The duration of treatment with peginterferon for HBeAg positive HBV is 48 weeks. The European Association for the Study of Liver (EASL) 2009 practice guideline\textsuperscript{17} also suggests peginterferon therapy for 48 weeks for both HBeAg positive and HBeAg negative HBV.

Peginterferon alfa-2a has an FDA approved indication for chronic hepatitis B while peginterferon alfa-2b is not FDA approved for chronic hepatitis B, however, there are studies that support its use for this indication.\textsuperscript{18}

**Peginterferon for the Treatment of Cancerous Conditions**\textsuperscript{19}

The off label use of peginterferon to treat various cancerous conditions including but not limited to hepatocellular carcinoma, gastrointestinal stromal tumors, kidney cancer, osteosarcoma, head and neck cancer, and melanoma is being investigated in several clinical trials. Peginterferon has been used as monotherapy, in combination with ribavirin, and in combination with other standard of care chemotherapy agents specific to the type of cancer being treated. Results of many clinical trials have either been preliminary or inconclusive, and many studies are ongoing. However, there is data reporting that response pattern to peginterferon is similar to the nonpegylated interferon.\textsuperscript{20}

For additional clinical information see Prime Therapeutics Formulary chapter 1.10D Antivirals: Hepatitis C.

**References:**

**Option 1: Peginterferon Prior Authorization – Through Preferred Agent**

**OBJECTIVE**
The intent of the Peginterferon Prior Authorization (PA) Criteria is to appropriately select patients for therapy according to the Food and Drug Administration (FDA) approved product labeling and/or clinical guidelines and/or clinical studies. The PA process will evaluate the use of peginterferon when there is supporting clinical evidence or prescriber-provided documentation supporting the unlabeled use. When criteria for use are met, the preferred agent, Pegasys, may be approved for use; use of the non-preferred peginterferon, PegIntron, will be evaluated if the prescriber indicates current use of PegIntron, a request for PegIntron for a cancerous or pre-cancerous condition, or a history of a trial and failure of, documented intolerance of, contraindication to, or hypersensitivity to the preferred interferon Pegasys.

**TARGET DRUGS**
Pegasys® (peginterferon alfa-2a)
PegIntron® (peginterferon alfa-2b)

**PRIOR AUTHORIZATION CRITERIA FOR APPROVAL**

**Pegasys or PegIntron** will be approved when ONE of the following is met:
1. Peginterferon is being prescribed for the treatment of a cancerous or pre-cancerous condition.

**Pegasys** (not for cancerous/pre-cancerous conditions) will be approved when BOTH of the following are met:
1. The patient has not been administered peginterferon for more than 24 months of total therapy
   **AND**
2. ONE of the following:
   a. Peginterferon is being prescribed for the treatment of acute or chronic hepatitis C infection confirmed by serological markers **OR**
   b. Peginterferon is being prescribed for the treatment of chronic hepatitis B virus infection confirmed by serological markers

**PegIntron** (not for cancerous/pre-cancerous conditions) will be approved when the criteria for Pegasys listed above are met AND ONE of the following is met:
1. The patient is currently being treated with the non-preferred agent, PegIntron (peginterferon alfa-2b)
   **OR**
2. ONE of the following:
   a. The patient has a history of a trial and failure of the preferred peginterferon, Pegasys **OR**
   b. The patient has a contraindication to, intolerance of, or allergy to the preferred peginterferon, Pegasys **OR**
   c. The prescriber has submitted documentation in support of the use of the non-preferred peginterferon, PegIntron, for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

**Length of Approval:**
- 24 months for confirmed hepatitis C virus infection
- 18 months for confirmed hepatitis B virus infection
- Indefinite for treatment of a cancerous or pre-cancerous condition
Option 1: Peginterferon Prior Authorization – Through Preferred Agent

**ELECTRONIC EDIT**
The overall process for a prior authorization will not allow the targeted drugs to adjudicate through the claims system. When a patient requests a targeted drug the system will reject the claim with the message indicating that prior authorization is necessary.

<table>
<thead>
<tr>
<th>Brand (generic)</th>
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<th>Multisource Code</th>
</tr>
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<tbody>
<tr>
<td><strong>Pegasys (peginterferon alfa-2a)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>180 mcg/ml injection</td>
<td>12353060056420</td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td><strong>PegIntron (peginterferon alfa-2b)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50 mcg/0.5 ml injection</td>
<td>12353060106410</td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td>80 mcg/0.5 ml injection</td>
<td>12353060106416</td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td>120 mcg/0.5 ml injection</td>
<td>12353060106424</td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td>150 mcg/0.5 ml injection</td>
<td>12353060106430</td>
<td>M, N, O, or Y</td>
</tr>
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</table>

**PRIOR AUTHORIZATION CRITERIA QUESTION SET**

**Prior Authorization Criteria for Approval**
The Prior Authorization (PA) Criteria for Approval provide the manual review process for all claims for targeted agents in this PA program.

**Option 1: through preferred agent, Pegasys Pegasys and PegIntron**

**Initial Evaluation**

1. Has the patient been previously approved for peginterferon through the Prime Therapeutics prior authorization approval process?  
   If yes, see renewal criteria. If no, continue to 2.

2. What is the diagnosis?  
   a. A cancerous or pre-cancerous condition  
   b. Chronic hepatitis B virus (HBV) infection  
   c. Acute or chronic hepatitis C (HCV) infection  
   d. Other  
   If a, continue to 8. If b, continue to 3. If c, continue to 5. If d, deny.

3. Has the patient previously received a course of interferon or peginterferon therapy?  
   If yes, deny. If no, continue to 4.

4. Has diagnosis of chronic HBV been confirmed by detection of serologic markers for the infection?  
   If yes, continue to 8. If no, deny.

5. Has the patient previously received a course of interferon or peginterferon therapy?  
   If yes, deny. If no, continue to 6.

6. Has the diagnosis of HCV been confirmed by detection of serologic markers for the infection?  
   If yes, continue to 7. If no, deny.

7. Has peginterferon been prescribed as a maintenance dose for HCV?  
   If yes, deny. If no, continue to 8.
8. Is the request for the *preferred* peginterferon agent, Pegasys?
   If yes, approve for a duration based on diagnosis:
   a. A cancerous or pre-cancerous condition - indefinitely
   b. Chronic hepatitis B virus (HBV) infection - 18 months (or the remainder of 18 months if the patient is already receiving a course of therapy)
   c. Acute or chronic hepatitis C (HCV) infection – initiation of a course of therapy – 6 months
   d. Acute or chronic hepatitis C (HCV) infection – continuation to finish a treatment course - remainder of course, up to 24 months
   If no, continue to 9.

9. Is the patient currently being treated with the *nonpreferred* agent, PegIntron?
   If yes, approve for a duration based on diagnosis:
   a. A cancerous or pre-cancerous condition - indefinitely
   b. Chronic hepatitis B virus (HBV) infection - remainder of 18 months
   c. Acute or chronic hepatitis C (HCV) infection – remainder of 24 months
   If no, continue to 10.

10. Does the patient have a history of a trial and failure of, or contraindication to, intolerance of, or allergy to the *preferred* agent, Pegasys?
    If yes, approve for a duration based on diagnosis:
    a. A cancerous or pre-cancerous condition - indefinitely
    b. Chronic hepatitis B virus (HBV) infection - 18 months (or the remainder of 18 months if the patient is already receiving a course of therapy)
    c. Acute or chronic hepatitis C (HCV) infection – initiation of a course of therapy – 6 months
    d. Acute or chronic hepatitis C (HCV) infection – continuation to finish a treatment course - remainder of course, up to 24 months
    If no, continue to 11.

11. Has the prescriber submitted and the pharmacist reviewed documentation in support of therapy with the *nonpreferred* agent, PegIntron?
    If yes, pharmacist must review and may approve for an appropriate duration of therapy based on review of information provided. If no, deny.

*Renewal Evaluation*

1. Has the patient been previously approved for peginterferon through the Prime Therapeutics prior authorization approval process?
   If yes, continue to 2. If no, see initial criteria.

2. What is the diagnosis?
   a. A cancerous or pre-cancerous condition
   b. Chronic hepatitis B virus (HBV) infection
   c. Acute or chronic hepatitis C (HCV) infection
   d. Other
   If a, continue to 5. If b, continue to 3. If c, continue to 4. If d, deny.

3. Has the patient received an 18 month course of peginterferon therapy?
   If yes, deny. If no, continue to 5.

4. Has the HCV RNA level at or before 6 months (24 weeks) of therapy become negative or decreased by at least two log10 units (such as from 2 million IU to 20,000 IU or less)?
   If yes, continue to 5. If no, deny.

5. Is the request for the *preferred* peginterferon agent, Pegasys?
If yes, approve for a duration based on diagnosis:
   a. A cancerous or pre-cancerous condition - indefinitely
   b. Chronic hepatitis B virus (HBV) infection - remainder of 18 months
   c. Acute or chronic hepatitis C (HCV) infection – remainder of 24 months
If no, continue to 6.

6. Is the patient currently being treated with the nonpreferred agent, PegIntron?
   If yes, approve for a duration based on diagnosis:
      a. A cancerous or pre-cancerous condition - indefinitely
      b. Chronic hepatitis B virus (HBV) infection - remainder of 18 months
      c. Acute or chronic hepatitis C (HCV) infection – remainder of 24 months
   If no, continue to 7.

7. Does the patient have a history of a trial and failure of, or contraindication to, intolerance of, or allergy to the preferred agent, Pegasys?
   If yes, approve for a duration based on diagnosis:
      a. A cancerous or pre-cancerous condition - indefinitely
      b. Chronic hepatitis B virus (HBV) infection - remainder of 18 months
      c. Acute or chronic hepatitis C (HCV) infection – remainder of 24 months
   If no, continue to 11.

8. Has the prescriber submitted and the pharmacist reviewed documentation in support of therapy with the nonpreferred agent, PegIntron?
   If yes, pharmacist must review and may approve for an appropriate duration of therapy based on review of information provided. If no, deny.
Option 2: Step Therapy through preferred, Pegasys

OBJECTIVE

The intent of the step therapy criteria is to direct use through the preferred agent and allows use of nonpreferred peginterferon if the patient has tried and failed, has an allergy, contraindication, or intolerance to the preferred agent or if the prescriber submits evidence in support of therapy with the nonpreferred agent.

TARGET DRUGS – STEP THERAPY

PegIntron® (peginterferon alfa-2b)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

PegIntron will be approved when ONE of the following is met:

1. Patient is currently being treated with the nonpreferred agent, PegIntron OR
2. Patient’s medication history indicate previous use of Pegasys OR
3. Patient has an allergy, contraindication, or intolerance to the preferred agent, Pegasys OR
4. Prescriber has provided and the pharmacist reviewed evidence in support of the use of the requested nonpreferred peginterferon product for the treatment of the intended diagnosis

Length of approval: 12 months

ELECTRONIC EDIT

The electronic step edit for the peginterferon agents will allow automatic payment of the preferred agent, Pegasys. The step edit will allow automatic payment of the nonpreferred agent, PegIntron, if the patient is being treated with PegIntron (claims history for the patient indicates a claim for PegIntron in the previous 90 days) or if the patient has tried Pegasys and is switching to PegIntron (claims history for the patient indicates a claim for Pegasys in the previous 90 days). The system searches for a claim with a days supply that begins or ends in the past 90 days. For claims with a 30 day supply the system would be able to identify a claim processed for payment between 1 and 120 days prior to the new claim. For claims that are dispensed as an extended days supply (90 days), the system would identify a claim processed between 1 and 180 days. Claims for PegIntron, not meeting the preferred agent edit, would be reviewed through a manual prior authorization process.

Summary of Peginterferon Step Therapy

<table>
<thead>
<tr>
<th>Targeted Agent</th>
<th>PegIntron</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is auto-grandfathering implemented? (with look-back time frame)</td>
<td>Yes (90 day look-back)</td>
</tr>
<tr>
<td>Prerequisite Agent</td>
<td>Pegasys</td>
</tr>
<tr>
<td>Number of prerequisites required</td>
<td>1</td>
</tr>
<tr>
<td>Prerequisite look-back time frame</td>
<td>90 days</td>
</tr>
<tr>
<td>Age-related edit?</td>
<td>No</td>
</tr>
</tbody>
</table>

Additional comments

a - The system searches for a claim with a days supply that begins or ends in the past 90 days. For claims with a 30-day supply the system would be able to identify a claim processed for payment between 1 and 120 days prior to the new claim. For claims that are dispensed as an extended days supply (90 days), the system would identify a claim processed between 1 and 180 days.
Details of Peginterferon Step Therapy

<table>
<thead>
<tr>
<th>Targeted Agents</th>
<th>GPI (multisource code)</th>
<th>Prior Agents</th>
<th>GPI (multisource code)</th>
<th>Look-back Time frames</th>
</tr>
</thead>
<tbody>
<tr>
<td>PegIntron</td>
<td>1235306005*** *</td>
<td>For Prerequisites</td>
<td>1235306010**** (M, N, O, or Y)</td>
<td>Prerequisite look-back time frame: 90 days^a</td>
</tr>
<tr>
<td></td>
<td>(M, N, O, or Y)</td>
<td>Pegasys</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>For Auto-grandfathering</td>
<td>1235306005**** (M, N, O, or Y)</td>
<td>Auto-grandfathering look-back time frame: 90 days^a</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PegIntron</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

^a - The system searches for a claim with a days supply that begins or ends in the past 90 days. For claims with a 30-day supply the system would be able to identify a claim processed for payment between 1 and 120 days prior to the new claim. For claims that are dispensed as an extended days supply (90 days), the system would identify a claim processed between 1 and 180 days.

If the patient does not meet the step therapy criteria, then the system will reject with the message indicating that prior authorization is necessary. The Prior Authorization (PA) Criteria for Approval would then be applied to requests submitted by the patient’s practitioner for evaluation.

PRIOR AUTHORIZATION CRITERIA QUESTION SET
PegIntron
Initial and Renewal Evaluation
1. Is the patient currently being treated with the nonpreferred agent, PegIntron?
   If yes, approve for 12 months. If no, continue to 2.

2. Does the patient’s medication history indicate previous use of Pegasys?
   If yes, approve for 12 months. If no, continue to 3.

3. Does the patient have an allergy, contraindication, or intolerance to the preferred agent, Pegasys?
   If yes, approve for 12 months. If no, continue to 4.

4. Has the prescriber provided and the pharmacist reviewed evidence in support of the use of the requested nonpreferred peginterferon product for the treatment of the intended diagnosis?
   If yes, pharmacist must review and may approve for 12 months. If no, deny.
Option 3: Peginterferon Prior Authorization all products-no product preference

OBJECTIVE
The intent of the Peginterferon Prior Authorization (PA) Criteria is to appropriately select patients for therapy according to the Food and Drug Administration (FDA) approved product labeling and/or clinical guidelines and/or clinical studies. The PA process will evaluate the use of peginterferon when there is supporting clinical evidence or prescriber-provided documentation supporting the unlabeled use.

TARGET DRUGS
Pegasys® (peginterferon alfa-2a)
PegIntron® (peginterferon alfa-2b)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL
Pegasys or PegIntron will be approved when ONE of the following is met:
1. Peginterferon is being prescribed for the treatment of a cancerous or pre-cancerous condition.
   OR
2. BOTH of the following:
   a. The patient has not been administered peginterferon for more than 24 months of total therapy
   AND
   b. ONE of the following:
      i. Peginterferon is being prescribed for the treatment of acute or chronic hepatitis C infection confirmed by serological markers
      OR
      ii. Peginterferon is being prescribed for the treatment of chronic hepatitis B virus infection confirmed by serological markers

Length of Approval:
24 months for confirmed hepatitis C virus infection
18 months for confirmed hepatitis B virus infection
Indefinite for treatment of a cancerous or pre-cancerous condition

Peginterferon Prior Authorization

ELECTRONIC EDIT
The overall process for a prior authorization will not allow the targeted drugs to adjudicate through the claims system. When a patient requests a targeted drug the system will reject the claim with the message indicating that prior authorization is necessary.

<table>
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<tr>
<th>Brand (generic)</th>
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<tbody>
<tr>
<td>Peginterferon alfa-2a</td>
<td></td>
<td></td>
</tr>
<tr>
<td>180 mcg/ml injection</td>
<td>12353060056420</td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td>Peginterferon alfa-2b</td>
<td></td>
<td></td>
</tr>
<tr>
<td>50 mcg/0.5 ml injection</td>
<td>12353060106410</td>
<td>M, N, O, or Y</td>
</tr>
<tr>
<td>80 mcg/0.5 ml injection</td>
<td>12353060106416</td>
<td>M, N, O, or Y</td>
</tr>
<tr>
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</table>
Option 3: Prior Authorization all products-no product preference

Pegasys and PegIntron

Initial Evaluation

1. Has the patient been previously approved for peginterferon through the Prime Therapeutics prior authorization approval process?
   If yes, see renewal criteria. If no, continue to 2.

2. What is the diagnosis?
   a. A cancerous or pre-cancerous condition
   b. Chronic hepatitis B virus (HBV) infection
   c. Acute or chronic hepatitis C (HCV) infection
   d. Other

   If a, approve indefinitely. If b, continue to 3. If c, continue to 5. If d, deny.

3. Has the patient previously received a course of interferon or peginterferon therapy?
   If yes, deny. If no, continue to 4.

4. Has diagnosis of chronic HBV been confirmed by detection of serologic markers for the infection?
   If yes, approve for 18 months (or the remainder of 18 months if the patient is already receiving a course of therapy). If no, deny.

5. Has the patient previously received a course of interferon or peginterferon therapy?
   If yes, deny. If no, continue to 6.

6. Has the diagnosis of HCV been confirmed by detection of serologic markers for the infection?
   If yes, continue to 7. If no, deny.

7. Has peginterferon been prescribed as a maintenance dose for HCV?
   If yes, deny. If no, continue to 8.

8. Is peginterferon being continued to finish a treatment course (member is currently receiving peginterferon)?
   If yes, approve for remainder of course, up to 24 months. If no, approve for 6 months.

Renewal Evaluation

1. Has the patient been previously approved for peginterferon through the Prime Therapeutics prior authorization approval process?
   If yes, continue to 2. If no, see initial criteria.

2. What is the diagnosis?
   a. A cancerous or pre-cancerous condition
   b. Chronic hepatitis B virus (HBV) infection
   c. Acute or chronic hepatitis C (HCV) infection
   d. Other

   If a, approve indefinitely. If b, continue to 3. If c, continue to 4. If d, deny.

3. Has the patient received an 18 month course of peginterferon therapy?
   If yes, deny. If no, approve for remainder of 18 months.

4. Has the HCV RNA level at or before 6 months (24 weeks) of therapy become negative or decreased by at least two log_{10} units (such as from 2 million IU to 20,000 IU or less)?
   If yes, approve for the remainder of 24 months. If no, deny.