1. **Background:**

**Indications**

Intron A (interferon alfa-2b) is indicated for the treatment of chronic hepatitis C in patients 18 years of age or older with compensated liver disease who have a history of blood or blood-product exposure and/or are HCV antibody positive. Intron A has additional FDA labeling for the treatment of chronic hepatitis C in patients 3 years of age and older with compensated liver disease previously untreated with alpha interferon therapy and in patients 18 years of age and older who have relapsed following alpha interferon therapy. Intron A is also indicated for the treatment of chronic hepatitis B in patients 1 year of age or older with compensated liver disease. Patients who have been serum HBsAg positive for at least 6 months and have evidence of HBV replication (serum HBeAg positive) with elevated serum ALT are candidates for treatment. Intron A is indicated for the treatment of patients 18 years of age or older with hairy cell leukemia. Intron A is indicated as adjuvant to surgical treatment in patients 18 years of age or older with malignant melanoma who are free of disease but a high risk for systemic recurrence, within 56 days of surgery. It is also indicated for the initial treatment of clinically aggressive follicular Non-Hodgkin’s lymphoma in conjunction with anthracycline-containing combination chemotherapy in patients 18 years of age or older. Intron A is indicated for intralesional treatment of selected patients 18 years of age or older with condylomata acuminata involving external surfaces of the genital and perianal areas. It is also indicated for the treatment of selected patients 18 years of age or older with AIDS-Related Kaposi’s Sarcoma.1

The National Comprehensive Cancer Network (NCCN) also recommends use of Intron A for leptomeningeal metastases, meningiomas, giant cell tumor of the bone, kidney cancer, melanoma, myeloproliferative neoplasms (MPNs) such as essential thrombocytopenia (ET), polycythemia vera (PV), and primary myelofibrosis (PM), adult T-cell leukemia / lymphoma, hairy cell leukemia, mycosis fungoides / Sézary syndrome, desmoid soft tissue sarcomas (aggressive fibromatosis), and systemic mastocytosis.2

Pegasys (peginterferon alfa-2a) is an antiviral indicated for the treatment of chronic hepatitis C (CHC) as part of a combination regimen with other hepatitis C virus (HCV) antiviral drugs in patients 5 years of age and older with compensated liver disease. Pegasys monotherapy is indicated for CHC only if patient has contraindication to or significant intolerance to other HCV antiviral drugs or in the treatment of adult patients with HBeAg positive and HBeAg negative chronic hepatitis B infection who have compensated liver disease and evidence of viral replication and liver inflammation.3
PegIntron (peginterferon alfa-2b), as part of a combination regimen, is indicated for the treatment of chronic hepatitis C in patients with compensated liver disease. PegIntron monotherapy should only be used in the treatment of CHC in patients with compensated liver disease if there are contraindications to or significant intolerance of ribavirin and is indicated for use only in previously untreated adult patients.4

The National Comprehensive Cancer Network (NCCN) also recommends the use of peginterferon alfa-2a and peginterferon alfa-2b in patients with myeloproliferative neoplasms (MPNs) such as essential thrombocytopenia (ET), polycythemia vera (PV), and primary myelofibrosis (PM), and systemic mastocytosis.9-12

Another formulation of peginterferon alfa-2b, Sylatron, is FDA approved for the adjuvant treatment of malignant melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy.5

2. Coverage Criteria:

A. Treatment of Hepatitis B

1. **Intron A, Pegasys, and PegIntron** will be approved based on all of the following criteria:

   a. Chronic Hepatitis B infection

      -AND-

   b. Patient without decompensated liver disease*

      **Authorization will be issued for 48 weeks.**

      *Defined as Child-Pugh Class B or C

B. Treatment of Chronic Hepatitis C (Intron A, Pegasys and PegIntron)

1. **Intron A, Pegasys or PegIntron** as part of a combination antiviral treatment regimen

   a. **Intron A, Pegasys or PegIntron** will be approved based on all of the following criteria:

      (1) Diagnosis of chronic hepatitis C infection

      -AND-

      (2) Patient without decompensated liver disease*

      -AND-
(3) Will be used as part of a combination antiviral treatment regimen

Authorization will be issued for 48 weeks.

*Defined as Child-Pugh Class B or C

C. For Diagnoses Other Than Hepatitis

1. PegIntron or Pegasys, will be approved based on one of the following diagnoses:
   a. For the treatment of myeloproliferative neoplasms (MPNs) such as essential
      thrombocythemia (ET), polycythemia vera (PV), or primary myelofibrosis (PM)
      -OR-
   b. Systemic mastocytosis

   Authorization will be issued for 12 months.

2. Sylatron will be approved based on one of the following diagnoses:
   a. Malignant melanoma
      -OR-
   b. For the treatment of myeloproliferative neoplasms (MPNs) such as essential
      thrombocythemia (ET), polycythemia vera (PV), or primary myelofibrosis (PM)
      -OR-
   c. Systemic mastocytosis

   Authorization will be issued for 12 months.

3. Intron A will be approved based on one of the following diagnoses:
   a. Hairy cell leukemia
   b. Condylomata acuminata (genital or perianal)
   c. AIDS-related Kaposi’s sarcoma
   d. Leptomeningeal metastases
   e. Meningiomas
   f. Kidney cancer
   g. For the treatment of myeloproliferative neoplasms (MPNs) such as essential
      thrombocythemia (ET), polycythemia vera (PV), or primary myelofibrosis (PM)
   h. Follicular lymphoma
   i. Adult T-cell leukemia / lymphoma
   j. Mycosis fungoides / Sézary syndrome
   k. Desmoid tumors / aggressive fibromatosis
l. Giant cell tumor of the bone  
m. Malignant Melanoma  
n. Systemic mastocytosis  

Authorization will be issued for 12 months.

D. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B  

Authorization will be issued for 12 months.

3. Additional Clinical Rules:
   
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.  
- Supply limits and/or Step Therapy may be in place.

4. References:

<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization/Notification - Infergen, Intron A, Pegasys, PegIntron, and Sylatron</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Change Control</strong></td>
<td></td>
</tr>
<tr>
<td>4/2014</td>
<td>For Pegasys and Peg-Intron, added patients with chronic hepatitis C genotype 3 as a patient population that may receive Sovaldi triple therapy.</td>
</tr>
<tr>
<td>2/2014</td>
<td>Removed all age criteria. Added criteria for triple therapy regimen including Olysio. Added criteria for triple therapy regimen including Sovaldi. Added criteria for giant cell tumor of the bone.</td>
</tr>
<tr>
<td>6/2015</td>
<td>Administrative change. Documented approval period for Pegasys “other indications”</td>
</tr>
<tr>
<td>11/2017</td>
<td>Annual review. Updated off-label NCCN recommendations for use. Removed CML (Intron A, Pegasys, PegIntron) and systemic light chain amyloidosis (Intron A) indications as no longer rec by NCCN. Updated references.</td>
</tr>
<tr>
<td>11/2018</td>
<td>Annual review. Updated background and criteria to include NCCN recommended use for systemic mastocytosis. Updated references.</td>
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