UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2022 P 1048-12
Program	Prior Authorization/Notification
Medications	Intron® A (interferon alfa-2b), Pegasys® (peginterferon alfa-2a), Besremi (ropeginterferon alfa-2b-njft)
P&T Approval Date	2/2004, 7/2007, 4/2009, 12/2009, 9/2010, 9/2011, 8/2012, 11/2012, 4/2013, 2/2014, 4/2014, 5/2015, 11/2016, 11/2017, 11/2018, 11/2019, 11/2020, 11/2021, 1/2022
Effective Date	4/1/2022; Oxford only: 4/1/2022

1. Background:

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(interferon alfa-2b) for giant cell tumors of the bone, mycosis fungoides/Sézary syndrome,primary cutaneous CD30+ T-cell lymphoproliferative disorders, and adult T-cell leukemia/lymphoma.[2]

Pegasys (peginterferon alfa-2a) is an inducer of the innate immune response 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. Pegasys is

indicated in the treatment of adult patients with HBeAg positive and HBeAg negative chronic hepatitis B (CHB) infection who have compensated liver disease and evidence of viral replication and liver inflammation. It is also indicated for the treatment of non-cirrhotic pediatric patients 3 years of age and older with HBeAg-positive CHB and evidence of viral replication and elevations in serum alanine aminotransferase (ALT).[3]

The National Comprehensive Cancer Network (NCCN) also recommends the use of Pegasys (peginterferon alfa-2a) in patients with chronic myeloid leukemia (CML), Erdheim-Chester disease (ECD), myeloproliferative neoplasms (MPNs) such as essential thrombocytopenia (ET), polycythemia vera (PV), and myelofibrosis (MF), and systemic mastocytosis, as well as mycosis fungoides/Sezary syndrome, hairy cell leukemia, primary cutaneous CD30+ T-cell lymphoproliferative disorders, and adult T-cell leukemia/lymphoma.

Besremi (ropeginterferon alfa-2b-njft) is an interferon alfa-2b indicated for the treatment of adults with polycythemia vera.[4]

2. Coverage Criteria:

A. Treatment of Hepatitis B

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

   a. Diagnosis of chronic hepatitis B infection

   -AND-

   b. Patient does not have decompensated liver disease*

   Authorization will be issued for 48 weeks.

   *Defined as Child-Pugh Class B or C

B. Treatment of Chronic Hepatitis C

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

   a. Diagnosis of chronic hepatitis C infection

   -AND-

   b. Patient does not have decompensated liver disease*

   -AND-

   c. 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. **Intron A** will be approved based on **one** of the following diagnoses:

   a. Hairy cell leukemia
   b. Malignant melanoma
   c. Follicular lymphoma
   d. Condylomata acuminata (genital or perianal)
   e. AIDS-related Kaposi's sarcoma
   f. Giant cell tumors of the bone
   g. Mycosis fungoides / Sézary syndrome
   h. Primary cutaneous CD30+ T-cell lymphoproliferative disorders
   i. Adult T-cell leukemia/lymphoma

   Authorization will be issued for 12 months.

2. **Pegasys** will be approved based on **one** of the following diagnoses:

   a. Chronic myeloid leukemia (CML)
   b. Hairy cell leukemia
   c. Systemic mastocytosis
   d. Erdheim-Chester disease (ECD)Hairy cell leukemia
   e. Myeloproliferative neoplasms (MPNs) such as essential thrombocythemia (ET), polycythemia vera (PV), or myelofibrosis (MF)
   f. Mycosis fungoides/Sezary syndrome
   g. Primary cutaneous CD30+ T-cell lymphoproliferative disorders
   h. Systemic mastocytosis
   i. Adult T-cell leukemia/lymphoma

   Authorization will be issued for 12 months.

3. **Besremi** will be approved based on the following criterion:

   a. Diagnosis of polycythemia vera

   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:

1. Intron A [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; August 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Accessed September 21, 2021 at http://www.nccn.org/professionals/drug_compendium/content/contents.asp
3. Pegasys [package insert]. South San Francisco, CA: Genentech USA, Inc.; March 2021.
4. Besremi [package insert]. Burlington, MA: PharmaEssentia; November 2021.

Program	Prior Authorization/Notification - Intron A, Pegasys, Besremi
Change Control	
4/2014	For Pegasys and Peg-Intron, added patients with chronic hepatitis C genotype 3 as a patient population that may receive Sovaldi triple therapy.
2/2014	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.
5/2015	Revised criteria for treatment of hepatitis C given market removal of Incivek, Infergen and pending removal of Victrelis. Criteria now reflects the shift in treatment of hepatitis C to non-interferon based therapies.
6/2015	Administrative change. Documented approval period for Pegasys "other indications"
11/2016	Annual review. Consolidation of hepatitis B and C criteria. Updated off-label NCCN recommendations for use. Updated references.
11/2017	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.

11/2018	Annual review. Updated background and criteria to include NCCN recommended use for systemic mastocytosis. Updated references.
11/2019	Annual review. Added general NCCN recommendations for use criteria. Updated references.
11/2020	Annual review. Updated background and criteria to include NCCN recommendations. Updated references.
11/2021	Annual review. Removed discontinued products, PegIntron and Sylatron. Updated background and criteria to align with label and NCCN guidelines. Updated references.
1/2022	Added criteria for Besremi. Updated references.