

## SPECIALTY GUIDELINE MANAGEMENT

### INTRON A (interferon alfa-2b)

#### POLICY

##### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

###### A. FDA-Approved Indications

1. AIDs-related Kaposi's sarcoma
2. Chronic hepatitis B virus infection
3. Chronic hepatitis C virus infection
4. Condylomata acuminata
5. Follicular non-Hodgkin's lymphoma
6. Hairy cell leukemia
7. Malignant melanoma

###### B. Compendial Uses

1. Acute hepatitis C virus infection
2. Chronic myelogenous leukemia (CML)
3. Desmoid tumors (soft tissue sarcoma)
4. Giant cell tumor of the bone
5. Renal cell carcinoma
6. Melanoma
7. Non-Hodgkin's lymphoma
  - a. Adult T-cell leukemia/lymphoma (ATLL)
  - b. Mycosis Fungoides (MF)/Sezary syndrome (SS)
8. Polycythemia vera
9. Systemic light chain amyloidosis

All other indications are considered experimental/investigational and are not a covered benefit.

##### II. CRITERIA FOR INITIAL APPROVAL

###### A. **Acute and Chronic Hepatitis C virus infection**

Authorization of up to 48 weeks may be granted for the treatment of acute and chronic hepatitis C virus infection.

###### B. **AIDs-related Kaposi's Sarcoma**

Authorization of 12 months may be granted for the treatment of AIDS-related Kaposi's sarcoma.

###### C. **Chronic Hepatitis B (including Hepatitis D Virus co-infection) virus infection**

Authorization of 48 weeks may be granted for treatment of chronic hepatitis B (including hepatitis D virus co-infection) virus infection

###### D. **Chronic Myelogenous Leukemia (CML)**

Authorization of 12 months may be granted to members who are prescribed Intron A for CML when member is unable to tolerate kinase inhibitor(s) or is post-hematopoietic stem cell transplant.

###### E. **Condylomata Acuminata**

Authorization of 12 months may be granted to members who are prescribed Intron A for the treatment of condylomata acuminata when the member is not a candidate for standard treatment options (e.g., podofilox, imiquimod, cryotherapy, podophyllin resin).

**F. Desmoid Tumors (soft tissue sarcoma)**

Authorization of 12 months may be granted for the treatment of desmoid tumors.

**G. Giant Cell Tumor of the Bone**

Authorization of 12 months may be granted for the treatment of giant cell tumor of the bone.

**H. Renal cell carcinoma**

Authorization of 12 months may be granted for the treatment of renal cell carcinoma.

**I. Malignant Melanoma**

Authorization of 12 months may be granted for the treatment of malignant melanoma.

**J. Non-Hodgkin's Lymphoma**

Authorization of 12 months may be granted for the treatment of ANY of the following conditions:

1. **Adult T-cell Leukemia/Lymphoma (ATLL)**
2. **Hairy Cell Leukemia**
3. **Mycosis Fungoides (MF)/Sezary Syndrome (SS)**
4. **Follicular Lymphoma (clinically aggressive)**

**K. Polycythemia Vera**

Authorization of 12 months may be granted for the treatment of polycythemia vera.

**L. Systemic Light Chain Amyloidosis**

Authorization of 12 months may be granted for the treatment of systemic light chain amyloidosis.

**III. CONTINUATION OF THERAPY**

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

**IV. DOSAGE AND ADMINISTRATION**

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

**V. REFERENCES**

1. Intron A [package insert]. Whitehouse Station, NJ: Schering Corporation; February 2016.
2. The NCCN Drugs & Biologics Compendium™ © 2015 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed April 01, 2016.
3. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. [www.micromedexsolutions.com](http://www.micromedexsolutions.com) [available with subscription]. Accessed April 01, 2016.
4. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; [http://online.lexi.com/lco/action/index/dataset/complete\\_ashp](http://online.lexi.com/lco/action/index/dataset/complete_ashp) [available with subscription]. April 01, 2016.
5. Clinical Consult. CVS Caremark Clinical Programs Review: Focus on Hematology-Oncology Clinical Programs. September 12, 2012.