

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 [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 [available with subscription]. April 01, 2016.
5. Clinical Consult. CVS Caremark Clinical Programs Review: Focus on Hematology-Oncology Clinical Programs. September 12, 2012.