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. **Condyломata 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., podophlox, 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. **DOSE 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**  