



## Prior Authorization Approval Criteria

### Department of Pharmacy Services

**Generic Name:** interferon alpha-2b, recombinant  
**Brand Name:** Intron A  
**Medication Class:** interferon/antiviral  
**FDA Approved Uses:** Hairy cell leukemia (HCL)  
Malignant melanoma (MM)  
Follicular lymphoma (FL)  
Condylomata acuminata (CA)  
AIDS-Related kaposi's sarcoma (ARKS)  
Chronic hepatitis C (CHC)  
Chronic hepatitis B (CHB)

#### Usual Doses/ Duration of Therapy:

*Hairy cell leukemia (HCL)*- 2 million IU/m<sup>2</sup> IM or SQ three times a week for up to 6 months.

*Malignant melanoma (MM)*- adjuvant treatment given in 2 phases- induction and maintenance:

-Induction-20million IU/m<sup>2</sup> as an IV infusion over 20 minutes  
5 days /week for 4 weeks.

-Maintenance- 10 million IU/m<sup>2</sup> as SQ three times a week for 48 weeks.

*Follicular lymphoma (FL)*- 5 million IU three times a week for up to 18 months in conjunction with anthracycline containing chemotherapy and following completion of the chemo regimen

*Condylomata acuminata (CA)*-1 million IU per lesion in a maximum of 5 lesions in a single course three times a week alternating days for 3 weeks. Additional courses may be administered at 12-16 weeks.

*AIDS-Related kaposi's sarcoma (ARKS)*- 30 million IU/m<sup>2</sup>/dose SQ or IM three times a week until disease progression or maximum response has been achieved after 16 weeks of treatment.

*Chronic hepatitis C (CHC)*- 3 million IU three times a week SQ or IM if tolerated treatment with normalization of ALT at 16 weeks therapy should be extended to 18-24 months at 3 million IU three times a week to improve sustained response rate.

*Chronic hepatitis B (CHB)*- 30-35 million IU three times a week SQ or IM either as 5 million IU qd or 10 million IU three times a week for 16 weeks.

#### Criteria for Use:

- **Hairy Cell Leukemia** for the treatment of patients 1 year of age or older with hairy cell leukemia.
- **Malignant Melanoma** as indicated as adjuvant to surgical treatment in patients 1 year of age or older with malignant melanoma who are free of disease but at high risk for systemic recurrence, within 56 days of surgery.
- **Follicular Lymphoma** for the initial treatment of clinically aggressive follicular Non-Hodgkin's Lymphoma in conjunction with anthracycline-containing combination chemotherapy in patients 1 year of age or older. Efficacy of INTRON A therapy in patients with low-grade, low-tumor burden follicular Non-Hodgkin's Lymphoma has not been demonstrated.



- **Condylomata Acuminata** for intralesional treatment of selected patients 1 year of age or older with condylomata acuminata involving external surfaces of the genital and perianal areas. The use of this product in adolescents has not been studied.
- **AIDS-Related Kaposi's Sarcoma** for the treatment of selected patients 1 year of age or older with AIDS-Related Kaposi's Sarcoma. The likelihood of response to INTRON A therapy is greater in patients who are without systemic symptoms, who have limited lymphadenopathy and who have a relatively intact immune system as indicated by total CD4 count.
- **Chronic Hepatitis C** for the treatment of chronic hepatitis C in patients 1 year of age or older with compensated liver disease who have a history of blood or blood- product exposure and/or are HCV antibody positive. Studies in these patients demonstrated that INTRON A therapy can produce meaningful effects on this disease, manifested by normalization of serum alanine aminotransferase (ALT) and reduction in liver necrosis and degeneration.
  - A liver biopsy should be performed to establish the diagnosis of chronic hepatitis. Patients should be tested for the presence of antibody to HCV. Patients with other causes of chronic hepatitis, including autoimmune hepatitis, should be excluded. Prior to initiation of INTRON A therapy, the physician should establish that the patient has compensated liver disease. The following patient entrance criteria for compensated liver disease were used in the clinical studies and should be considered before INTRON A treatment of patients with chronic hepatitis C:
    - No history of hepatic encephalopathy, variceal bleeding, ascites, or other clinical signs of decompensation
    - Bilirubin  $\leq 2$  mg/dL
    - Albumin Stable and within normal limits
    - Prothrombin Time  $< 3$  seconds prolonged
    - WBC  $\geq 3000/\text{mm}^3$
    - Platelets  $\geq 70,000/\text{mm}^3$

Serum creatinine should be normal or near normal.

Prior to initiation of INTRON A therapy, CBC and platelet counts should be evaluated in order to establish baselines for monitoring potential toxicity. These tests should be repeated at weeks 1 and 2 following initiation of INTRON A therapy and monthly thereafter. Serum ALT should be evaluated at approximately 3-month intervals to assess response to treatment

Patients with preexisting thyroid abnormalities may be treated if thyroid-stimulating hormone (TSH) levels can be maintained in the normal range by medication. TSH levels must be within normal limits upon initiation of INTRON A treatment and TSH testing should be repeated at 3 and 6 months.



INTRON A in combination with REBETOL (ribavirin, USP) Capsules is indicated for the treatment of chronic hepatitis C in patients 3 years of age or older with compensated liver disease previously untreated with alfa interferon therapy and in patients 18 years of age and older who have relapsed following alfa interferon therapy. See REBETOL Combination Therapy package insert for additional information.

**Chronic Hepatitis B** 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.
- Studies in these patients demonstrated that INTRON A therapy can produce virologic remission of this disease (loss of serum HBeAg), and normalization of serum aminotransferases.

Prior to initiation of INTRON A therapy, it is recommended that a liver biopsy be performed to establish the presence of chronic hepatitis and the extent of liver damage. The physician should establish that the patient has compensated liver disease. The following patient entrance criteria for compensated liver disease were used in the clinical studies and should be considered before INTRON A treatment of patients with chronic hepatitis B:

- No history of hepatic encephalopathy, variceal bleeding, ascites, or other signs of clinical decompensation
- Bilirubin Normal
- Albumin Stable and within normal limits
- Prothrombin *Adults* <3 seconds *Pediatrics* <=2  
Time prolonged seconds prolonged
- WBC >=4000/mm<sup>3</sup>
- Platelets *Adults* *Pediatrics*  
>=100,000/mm<sup>3</sup> >=150,000/mm<sup>3</sup>

**Contraindications:**

- Patients with causes of chronic hepatitis other than chronic hepatitis B or chronic hepatitis C should not be treated with INTRON A Interferon alfa-2b, recombinant for Injection.
- Hypersensitivity to interferon alpha or any other component of the product.
- Patients with autoimmune hepatitis should not be treated with Intron A/ Rebetol combination therapy.
- Decompensated liver disease.

**Not approved if:**

- Patient has any contraindications to the use of PEG-Intron.
- Patient does not meet the above stated criteria.

P&T Approval: \_\_\_\_\_ Date: \_\_\_\_\_