PHARMACY PRE-AUTHORIZATION CRITERIA

DRUG (S)	**Intron-A (interferon alfa-2b, recombinant)**
POLICY #	**22129, J-9214**
INDICATIONS	• Intron A is indicated for the treatment of patients of 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 at high risk for systemic recurrence, within 56 days of surgery • Intron A is indicated for the initial treatment of clinically aggressive follicular Non-Hodgkins's lymphoma in conjunction with anthracycline-containing chemotherapy in patient 18 years of age or older. • Intron A is indicated for intralesional treatment of selected patients 18 years of age or older with condylomata acuminate involving external surfaces of the genital and perianal areas • Intron A is indicated for the treatment of selected patients 18 years of age or older with AIDS-Related Kaposi's Sarcoma. • Intron A 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 is indicated for the treatment of chronic hepatitis B in patients 1 year of age or older with compensated liver disease
CRITERIA	ConnectiCare considers Intron-A to be medically necessary in patients 18 years of age or older when any of following indications are met: ➢ hairy cell leukemia ➢ malignant melanoma ➢ non-Hodgkin's lymphoma in conjunction with anthracycline-containing combination chemotherapy ➢ Condylomata acuminata (genital and perianal area), intralesional only ➢ Acquired immune deficiency syndrome (AIDS)- associated Kaposi's sarcoma ➢ Chronic hepatitis C- a. Patient must be seen by a gastroenterologist, infectious disease physician, hepatologist, or a transplant physician b. Clinically documented chronic hepatitis C with detectable HCV RNA levels > 50 IU/ml and compensated liver disease (viral load and genotype lab report required) c. Patient must have a contraindication or intolerance to Pegasys (*ConnectiCare's preferred pegylated interferon) Pegylated interferon in combination with ribavirin is the current standard of care to treat chronic hepatitis C. d. No history of hepatic encephalopathy, variceal bleeding,ascites, or other clinical signs of decompensation e. Bilirubin</= 2 mg/dl f. Albumin stable and within normal limits

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g. Prothombin time <3 seconds prolonged
h. WBC>/= 3000/mm^3
i. Platelets >/= 70,000/mm^3

- Chronic hepatitis B- (includes pediatric patients)
  a. Patient must be seen by a gastroenterologist, infectious disease physician, hepatologist, or a transplant physcian
  b. Patient has been serum HBsAg positive for at least 6 months and have evidence of HBV replication (serum HBeAg positive) with elevated serum ALT
  c. Patient must have a contraindication or intolerance to Pegasys
  d. Patient has HBV DNA >20,000 IU/ml
  e. No history of hepatic encephalopathy, variceal bleeding,ascites, or other clinical signs of decompensation
  f. Bilirubin normal
  g. Albumin stable and within normal limits
  h. Prothombin: Adults-<3 seconds Pediatrics </=2 seconds
  i. WBC >/= 4000/ mm^3
  j. Platelets: Adults >/= 100,000/ mm^3 Pediatrics: >/= 150,000/ mm^3

- Chronic myelocytic leukemia
- Polycythemia vera (non-FDA approved indication) when all of the following are met:
  a. Phlebotomy is not effective, not tolerated, or contraindicated *and*
  b. Oral therapy with hydroxyurea or other myelosuppressive agents are not effective, not tolerated, or contraindicated

Note: Failure of phlebotomy and/or myelosuppressive agents may be defined as any of the following:

a. Lack of hematological control (e.g., hematocrit greater than 45 or platelet count greater than 600 X 109/L)
b. Phlebotomy required more often than once every two months

- Superficial bladder cancer-carcinoma in situ of the bladder (non-FDA labeled indication)
- Renal cell carcinoma (non-FDA indication indication)
- Cutaneous T-cell lymphoma (non-FDA approved indication)

LIMITATIONS	**Dosing and Administration:**

Hairy cell leukemia- 2 MU/m^2 IM or SC three 3 times a week for up to 6 months
Malignant melanoma- 20 MU/ m^2 by IV infusion, 5 days per week, for 4 weeks followed by 10 MU/ m^2 SC 3 times a week for 48 weeks.

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	Follicular lymphoma -5 MU SC 3 times a week for up to 18 months in conjunction with anthracycline-containing chemotherapy Condylomata Acuminata- 1 MU per lesion 3 times weekly for 3 weeks AIDS-Related Kaposi's Sarcoma- 30 MU/ m^2 SC or IM 3 times a week until disease progression or maximal response has been achieved after 16 weeks of treatment Chronic Hepatits C- 3MU three times a week SC or IM. In patients tolerating therapy with normalization of ALT at 16 weeks treatment therapy should be extended to 18 to 24 months at 3 MU three times a week to improve sustained response Rate. Patients that do not normalize their ALTs after 16 weeks of therapy may not be authorized further treatment. Chronic Hepatits B- (adults) 30 to 35 MU per week SC or IM for 16 weeks (Pediatric) 3 MU/m^2 SC three times per week times one week followed by 6 MU/m^2 SC three times weekly for a total of 16-24 weeks A variety of dosage schedules of interferon have been used for the unlabeled indications.
REFERENCES	1. Quesada JR, Rios A, Swanson D, Trwon P, Gutterman JU. Antitumor activity of recombinant-derived interferon-alpha after transurethral resection of superficial bladder cancer:a randomized prospective study. Urol Int. 2004;72(4):284-91. 2. Joudi FN, Smith BJ, O'Donnell MA; National BCG-Interferon Phase 2 Investigator Group. Final results from a national multicenter phase II trial of combination bacillus Calmette-Guerin (BCG) plus interferon alfa 2b for recurrence of superficial bladder cancer. Urol. Oncol. 2006 July-Aug;24(4):344-8. 3. USPDI, Drug Information for the Health Care Professional. 26th ed. Greenwood Village, CO: Micromedex Thomson Healthcare. 4. Facts & Comparisons online
P&T REVIEW HISTORY	3/05, 6/07, 6/08, 9/09, 9/10, 12/11, 10/12, 10/13, 10/14, 11/15, 5/16, 5/17, 5/18, 5/19
REVISION RECORD	11/12, 5/17