1703-A

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

B. Compendial Uses

- 1. Adult T-cell leukemia/lymphoma (ATLL)
- 2. Mycosis fungoides (MF)/Sezary syndrome (SS)
- 3. Myeloproliferative neoplasms
 - i. Essential thrombocythemia
 - ii. Mvelofibrosis
 - iii. Polycythemia vera
- 4. Renal cell carcinoma
- 5. Chronic myeloid leukemia (CML)
- 6. Giant cell tumor of the bone
- 7. Desmoid tumors (soft tissue sarcoma)
- 8. Systemic mastocytosis
- 9. Carcinoid syndrome
- 10. Hypereosiniphilic syndrome
- 11. Ocular surface neoplasia (conjunctival and corneal neoplasm)
- 12. Respiratory papillomatosis
- 13. Refer to Section II, Criteria for Initial Approval, for additional approvable regimens

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Malignant melanoma

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

B. Adult T-cell leukemia/lymphoma (ATLL)

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Authorization of 12 months may be granted for treatment of adult T-cell leukemia/lymphoma (ATLL) when the requested medication is used in combination with either zidovudine or arsenic trioxide.

C. Mycosis fungoides (MF)/Sezary syndrome (SS)

Authorization of 12 months may be granted for treatment of mycosis fungoides (MF)/Sezary syndrome (SS).

D. Hairy cell leukemia

Authorization of 12 months may be granted for treatment of hairy cell leukemia.

E. Follicular lymphoma

Authorization of 12 months may be granted for treatment of follicular lymphoma (clinically aggressive).

F. Renal cell carcinoma

Authorization of 12 months may be granted for treatment of renal cell carcinoma when the requested medication will be used in combination with bevacizumab.

G. Condylomata acuminata

Authorization of 12 months may be granted for treatment of condylomata acuminata.

H. AIDS-related Kaposi sarcoma

Authorization of 12 months may be granted for treatment of AIDS-related Kaposi sarcoma

I. Chronic myeloid leukemia (CML)

Authorization of 6 months may be granted for treatment of CML.

J. Giant cell tumor of the bone

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

K. Desmoid tumors (soft tissue sarcoma) Authorization of 12 months may be granted for treatment of desmoid tumors when used as a single agent.

L. Chronic hepatitis C virus infection Authorization of 16 weeks may be granted for treatment of chronic hepatitis C virus infection.

M. Chronic hepatitis B (including hepatitis D virus co-infection) virus infection

Authorization of 16 weeks may be granted for treatment of chronic hepatitis B (including hepatitis D virus co-infection) virus infection.

N. Myeloproliferative neoplasms

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

- 1. Symptomatic low-risk myelofibrosis
- 2. Essential thrombocythemia
- 3. Polycythemia vera

O. Systemic mastocytosis

Authorization of 12 months may be granted for treatment of systemic mastocytosis when either of the following criteria are met:

- 1. The requested medication will be used as a single agent, or
- 2. The requested medication will be used in combination with prednisone.

P. Hypereosinophilic syndrome

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Authorization of 12 months may be granted for treatment of hypereosinophilic syndrome when the member has had an inadequate response or has contraindication to corticosteroids.

Q. Carcinoid syndrome

Authorization of 12 months may be granted for treatment of carcinoid syndrome.

R. Ocular surface neoplasia (conjunctival and corneal neoplasm)

Authorization of 12 months may be granted for treatment of ocular surface neoplasia (conjunctival and corneal neoplasm).

S. Respiratory papillomatosis

Authorization of 12 months may be granted for treatment of respiratory papillomatosis.

III. CONTINUATION OF THERAPY

A. Chronic Hepatitis C

Authorization of 52 weeks, up to a total of 96 weeks, may be granted for continued treatment of chronic hepatitis C when the member is receiving clinical benefit and there is no evidence of unacceptable toxicity while on the current regimen.

B. Chronic Hepatitis B

Authorization of up to a total of 24 weeks may be granted for continued of chronic hepatitis B when the member is receiving clinical benefit and there is no evidence of unacceptable toxicity while on the current regimen.

C. All Other Indications

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II, other than chronic hepatitis C and chronic hepatitis B, when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

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