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. Condylomata 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. Non-Hodgkin's lymphoma
 - i. Adult T-cell leukemia/lymphoma (ATLL)
 - ii. Mycosis fungoides (MF)/Sezary syndrome (SS)
- 2. Myeloproliferative neoplasms
 - i. Essential thrombocythemia
 - ii. Myelofibrosis
 - iii. Polycythemia vera
- 3. Renal cell carcinoma
- 4. Chronic myelogenous leukemia (CML)
- 5. Giant cell tumor of the bone
- 6. Acute hepatitis C virus infection
- 7. Desmoid tumors (soft tissue sarcoma)
- 8. Systemic mastocytosis
- 9. Carcinoid syndrome
- 10. Hypereosiniphilic syndrome
- 11. Kasabach-Merritt syndrome
- 12. Leptomeningeal metastases
- 13. Life threatening hemangioma of infancy
- 14. Meningeoma
- 15. Neuroendocrine tumors of the GI tract, lung, or thymus (carcinoid tumors)
- 16. Ocular surface neoplasia (conjunctival and corneal neoplasm)
- 17. Respiratory papillomatosis
- 18. Vulvar vestibulitis

All other indications are considered experimental/investigational and are not a covered benefit.

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II. CRITERIA FOR INITIAL APPROVAL

A. Malignant melanoma

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

B. Non-Hodgkin's lymphoma (NHL)

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

- 1. Adult T-cell leukemia/lymphoma (ATLL) when used in combination with either of the following:
 - a. Zidovudine, or
 - b. Arsenic trioxide
- 2. Mycosis fungoides (MF)/Sezary syndrome (SS)
- 3. Hairy cell leukemia when used as a single agent
- 4. Follicular lymphoma (clinically aggressive)

C. Renal cell carcinoma

Authorization of 12 months may be granted for treatment of renal cell carcinoma when both of the following criteria are met:

- 1. Intron-A will be used in combination with bevacizumab.
- 2. The disease is of clear-cell histology.

D. Condylomata acuminata

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

E. AIDS-related Kaposi sarcoma

Authorization of 12 months may be granted for treatment of AIDS-related Kaposi sarcoma when both of the following are met:

- 1. Intron-A is used for subsequent therapy.
- 2. Intron-A will be given with antiretroviral therapy (ART).

F. Chronic myelogenous leukemia (CML)

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

G. Giant cell tumor of the bone

Authorization of 12 months may be granted for treatment of giant cell tumor of the bone when either of the following criteria are met:

- 1. Intron-A will be used as a single agent, or
- 2. Intron-A will be used in combination with denosumab.

H. Desmoid tumors (soft tissue sarcoma)

Authorization of 12 months may be granted for treatment of desmoid tumors when used as a single agent.

I. Acute and chronic hepatitis C virus infection

Authorization of up to 48 weeks may be granted for treatment of acute and chronic hepatitis C virus infection.

J. 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.

K. Myeloproliferative neoplasms

Authorization of 12 months may be granted for treatment of symptomatic low-risk myelofibrosis, essential thrombocythemia, and polycythemia vera.

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L. Systemic mastocytosis

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

- 1. Intron-A will be used as a single agent, or
- 2. Intron-A will be used in combination with prednisone.

M. Hypereosinophilic syndrome

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

N. Kasabach-Merritt syndrome

Authorization of 12 months may be granted for treatment of Kasabach-Merritt syndrome.

O. Leptomeningeal metastases

Authorization of 12 months may be granted for treatment of leptomeningeal metastases.

P. Life threatening hemangioma of infancy

Authorization of 12 months may be granted for treatment of life threatening hemangioma in an infant patient who has had an inadequate response or contraindication to corticosteroids.

Q. Meningeoma

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

- 1. The disease is recurrent, or
- 2. The disease is surgically inaccessible.

R. Neuroendocrine tumors of the GI tract, lung, or thymus (carcinoid tumors)

Authorization of 12 months may be granted for treatment of neuroendocrine tumors of the GI tract, lung, or thymus.

S. Carcinoid syndrome

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

T. Ocular surface neoplasia (conjunctival and corneal neoplasm)

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

U. Respiratory papillomatosis

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

V. Vulvar vestibulitis

Authorization of 12 months may be granted for treatment of vulvar vestibulitis

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II who have not experienced disease progression or an unacceptable toxicity.

IV. REFERENCES

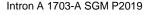
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