Reference number(s)
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. 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.

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.

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

Reference number(s)
1703-A

1. Intron A [package insert]. Whitehouse Station, NJ: Schering Corporation; October 2017.
2. The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed April 28, 2019.
3. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com/. Accessed April 28, 2019.
4. Lexicomp Online®, AHFS® Drug Information, Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; http://online.lexi.com [available with subscription]. Accessed April 28, 2019.
5. Clinical Consult. CVS Caremark Clinical Programs Review: Focus on Hematology-Oncology Clinical Programs. September 12, 2012.
6. Roufosse FE, Goldman M, Cogan E. Hypereosinophilic syndromes. *Orphanet J Rare Dis.* 2007;2:37.
7. Wananukul S, Nuchprayoon I, Seksarn P. Treatment of Kasabach-Merritt syndrome: a stepwise regimen of prednisolone, dipyridamole, and interferon. *Int J Dermatol.* 2003;42:741.
8. Gerber S, Bongiovanni, et al. A deficiency in interferon-alpha production in women with vulvar vestibulitis. Obstet Gynecol 2002 Mar;186(3):361-4.
9. Leventhal BG, Kashima HK, Mounts P, et al. Long-term response of recurrent respiratory papillomatosis to treatment with lymphoblastoid interferon alfa-n-1. *N Engl J Med.* 1991;325:613-617.
10. Frieden IJ, Eichenfield LF, Esterly NB, et al. Guidelines of care of hemangiomas of infancy. American Academy of Dermatology/Outcome Committee. *J Am Acad Dermatol.* 1997;37(4):631-637.
11. Shah SU, Kaliki S, Kim HJ, Lally SE, Shields JA, Shields CL. Topical Interferon Alfa-2b for Management of Ocular Surface Squamous Neoplasia in 23 Cases: Outcomes Based on American Joint Committee on Cancer Classification. *Arch Ophthalmol.* 2012;130(2):159–164.
12. Chamberlain MC. A phase II trial of intra-cerebrospinal fluid alpha interferon in the treatment of neoplastic meningitis. *Cancer.* 2002; 94:2675-2680.
13. Kaba SE, De Monte F, Bruner JM et al. The treatment of recurrent unresectable and malignant meningiomas with interferon alpha2B. *Neurosurgery.* 1997;40:271-275.