

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. Adult T-cell leukemia/lymphoma (ATLL)
2. Mycosis fungoides (MF)/Sezary syndrome (SS)
3. Myeloproliferative neoplasms
 - i. Essential thrombocythemia
 - ii. Myelofibrosis
 - 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. Hypereosinophilic 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)**

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

Reference number(s)
1703-A

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

1. Intron A [package insert]. Whitehouse Station, NJ: Schering Corporation; August 2019.
2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed April 06, 2020.
3. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com/>. Accessed April 14, 2020.
4. Lexicomp Online®, AHFS® Drug Information, Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc.; <http://online.lexi.com> [available with subscription]. Accessed April 14, 2020.
5. AHFS Drug Information. <http://online.lexi.com/lco>. Accessed April 14, 2020.
6. Roufosse FE, Goldman M, Cogan E. Hypereosinophilic syndromes. *Orphanet J Rare Dis*. 2007;2:37.
7. 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.
8. 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.
9. National Organization for Rare Disorders (NORD). <https://rarediseases.org>. Accessed April 14, 2020.
10. Avastin [package insert]. South San Francisco, CA: Genentech, Inc.; June 2019.
11. NCCN Clinical Practice Guidelines in Oncology® Bone Cancer (Version 1.2020). © 2020 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed April 08, 2020.

Reference number(s)
1703-A

12. American Academy of Ophthalmology (AAO). Ocular surface squamous neoplasia. EyeWiki. San Francisco, CA: AAO; last modified on November 8, 2017
13. Karp CL, Galor A, Chhabra S, Barnes SD, Alfonso EC. Subconjunctival/perilesional recombinant interferon alpha2b for ocular surface squamous neoplasia: a 10-year review. Ophthalmology. 2010;117(12):2241–6.
14. Shields CL, Kaliki S, Kim HJ, Al-Dahmash S, Shah SU, Lally SE, et al. Interferon for ocular surface squamous neoplasia in 81 cases: outcomes based on the American Joint Committee on Cancer classification. Cornea. 2013;32(3):248–56.