Intron® A (interferon alfa-2b)

Effective: 10/1/15

Clinical documentation and prior authorization required ✓ Type of review – case management
Not covered Type of review – clinical review
Fax: 617-673-0988 ✓
Pharmacy (RX) or medical (MED) benefit RX Department to review RxUM

OVERVIEW

FDA-APPROVED INDICATIONS

**Intron A (interferon alfa-2b) is for:**

**Hairy Cell Leukemia**
Intron A is indicated for the treatment of patients 18 years of age or older with hairy cell leukemia.

**Malignant Melanoma**
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.

**Follicular Lymphoma**
Intron A is indicated for the initial treatment of clinically aggressive (see Clinical Pharmacology) follicular Non-Hodgkin’s Lymphoma in conjunction with anthracycline-containing combination chemotherapy in patients 18 years of age or older.

**Condylomata Acuminata**
INTRON A is indicated for intralesional treatment of selected patients 18 years of age or older with condylomata cuminata involving external surfaces of the genital and perianal areas.

**AIDS-Related Kaposi’s Sarcoma**
Intron A is indicated for the treatment of selected patients 18 years of age or older with AIDS-Related Kaposi’s Sarcoma.

**Chronic Hepatitis C**
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.

**Chronic Hepatitis B**
Intron A is indicated for the treatment of chronic hepatitis B in patients 1 year of age or older with compensated liver disease.

PHARMACY COVERAGE GUIDELINES

Tufts Health Plan – Network Health may authorize coverage of Intron A (Interferon alfa-2b) for members when all the following criteria are met:

1. The member has been evaluated by a gastroenterologist, oncologist or infectious disease specialist AND

**Chronic Hepatitis B**
1. The member has a diagnosis of Chronic Hepatitis B AND
2. The member has serum markers of hepatitis B virus (HBV) replication (HBeAg and HBV DNA).

**Chronic Hepatitis C**
1. The member has a diagnosis of Chronic Hepatitis C AND
2. The member is not receiving another interferon product AND
3. The member has a viral level positive for hepatitis C AND
4. The member persistently has elevated serum alanine aminotransferase (ALT) levels OR
5. The member has a liver biopsy demonstrating histological evidence of liver injury.

**Hairy Cell Leukemia**
1. The member has a diagnosis of Hairy Cell Leukemia.

**Kaposi’s Sarcoma**
1. The member has a diagnosis of Kaposi’s Sarcoma.
Malignant Melanoma
1. The member has a diagnosis of Malignant Melanoma.

Condylomata Acuminata
1. The member has a diagnosis of Condylomata Acuminata.

Follicular Lymphoma
1. The member has a diagnosis of Follicular Lymphoma.

LIMITATIONS
1. Initial requests will be approved for the following durations:
   a. Chronic Hepatitis B, Chronic Hepatitis C, Hairy Cell Leukemia, Kaposi’s Sarcoma: 6 months.
   b. Malignant Melanoma, Follicular Lymphoma: 12 months.
   c. Condylomata Acuminata: 1 month.

2. Subsequent authorizations for Chronic Hepatitis C will be approved for 6 months (maximum of 24 months) when criteria a, b and c are met or the remainder of 12 months if criteria a, b and d are met:
   a. The member has viral levels positive for Hepatitis C after or at the end of the initial treatment period AND
   b. The member has normalization of serum alanine aminotransferase (ALT) levels during the initial treatment period AND
   c. The member was treated before with interferon monotherapy OR
   d. The member was treated before with combination therapy.

3. Subsequent authorizations for Hairy Cell Leukemia, Kaposi’s Sarcoma, Malignant melanoma and follicular Lymphoma will be approved for 12 months.

4. Subsequent authorizations for Condylomata Acuminata will be approved for 1 month.

CODES
None

REFERENCES

APPROVAL HISTORY
• October 7, 2014: Reviewed by the Pharmacy and Therapeutics Committee.
• September 16, 2015: No changes

BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION
Pharmacy Medication Request Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). Pharmacy Medication Request Guidelines are developed for selected therapeutic classes or drugs found to be safe but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medication Request Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.
Pharmacy Medication Request Guidelines apply to all insured offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the applicable Preferred Drug List (formulary) in the pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to the Tufts Health Unify Prior Authorization Medical Necessity Guidelines.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines, when applicable, and adherence to plan policies and procedures and claims editing logic.