Generic Name: Pegylated Interferon alfa-2a

Applicable Drugs: Pegasys®

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 12/8/2023

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Documentation of diagnosis of A, B, or C and must meet ALL applicable criteria:

A. Chronic hepatitis B (CHB) (refer to Appendix Table 1 for criteria by population)

i. For adults age 18 and older, there must be documentation of all criteria 1, 2 and, 3 (when applicable), as well as one of criteria 4, 5, OR 6:

1. HBsAg positive for ≥ 6 months.
2. Baseline HBV-DNA level.
3. Genotypic viral testing showing sensitivity and treatment history (only required for treatment-experienced patients).
4. Evidence of significant histologic disease* by fibrosis assessment testing* (see appendix for details).
5. ALT >2 times the ULNc AND HBV-DNA >2,000 IU/mL (HBeAg negative) or >20,000 IU/mL (HBeAg positive)
6. ALT < 2 times the ULN AND HBV DNA ≤ 2,000 IU/mL (HBeAg negative) or ≤ 20,000 IU/mL (HBeAg positive) with ONE of the following risk factors:
    a. Age > 40 years old
    b. Family history of cirrhosis or hepatocellular carcinoma
    c. Previous treatment history
    d. Presence of extrahepatic manifestations
    e. Cirrhosis

ii. For pediatric patients aged 3 to ≤ 18 years, there must be documentation of ALL of the following:

1. HBsAg positive for ≥ 6 months
2. HBeAg positive
3. ALT > 1.3 times the ULNa for at least 6 months
4. Measurable HBV-DNA levels

B. Chronic Hepatitis D meeting criteria i and ii:
    i. Documented elevated HDV-RNA levels.
    ii. Documented elevated serum ALT levels.
C. Off-label NCCN guideline recommended diagnosis (refer to **Appendix Table 1** for list of diagnoses)
    i. Chronic myeloid leukemia
    ii. Erdheim-Chester disease (as second line therapy)
    iii. Essential thrombocythemia
    iv. Hairy cell leukemia
    v. Mycosis fungoides/Sezary syndrome
    vi. Myelofibrosis
    vii. Primary cutaneous CD30+ T-cell lymphoproliferative disorders
    viii. Polycythemia vera (as second line therapy)
    ix. Systemic mastocytosis

II. Medication is prescribed in accordance with FDA labeling and is supported by current clinical practice guidelines.

III. Treatment must be prescribed by or in consultation with a gastroenterologist, infectious disease specialist, hepatologist, or oncologist.

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Autoimmune hepatitis.
- Decompensated liver disease (Child-Pugh B or C)

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 4 syringes/vials per 28 days.

APPROVAL LENGTH

- **Authorization:**

- Hepatitis B or D: 48 weeks
- NCCN diagnoses: 12 months

- **Re-Authorization:**
  - Hepatitis B or D: N/A
  - NCCN diagnoses: Progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

- ***** Evidence of significant histologic disease may include results such as moderate-to-severe inflammation (A2 or A3) and/or significant fibrosis (≥F2).
- ***** Fibrosis assessment testing may include tests such as liver biopsy, FIB-4, FibroScan, Fibrotest, or Fibrosure.
- The ULN (upper limit of normal) for ALT is defined as 35 U/L for males and 25 U/L females.
- Abbreviations: ALT, alanine aminotransferase; CHB, chronic hepatitis B; HBeAg, hepatitis B e antigen; HBsAg, hepatitis B surface antigen; NA, nucleos(t)ide analogue; ULN, upper limits of normal.

Table 1. Pegylated interferon NCCN Treatment Recommendations by Diagnosis[3-16]

Diagnosis	Recommendation
Chronic myeloid leukemia	• Treatment during pregnancy
Erdheim-Chester disease	• First line or subsequent disease
Essential thrombocythemia	• High risk disease
Hairy cell leukemia	• Relapsed or refractory disease
Mycosis fungoides/Sezary syndrome	• Mycosis fungoides stage IA, IB-IIA, IIB, III: primary or subsequent treatment • Sezary syndrome stage IVA1 or IVA2: primary or subsequent treatment
Myelofibrosis	• Lower risk, symptomatic disease
Primary cutaneous CD30+ T-cell lymphoproliferative disorders	• Primary cutaneous ALCL with multifocal lesions: primary or relapsed/refractory disease
Polycythemia vera	• High risk disease
Systemic mastocytosis	• Advanced indolent or smoldering systemic mastocytosis • Aggressive systemic mastocytosis • Systemic mastocytosis with an associated hematologic neoplasm
T-Cell lymphomas	• Adult T-cell leukemia/lymphoma: acute or chronic smoldering (in combination with zidovudine)

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DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.