

Applicable Drugs: Pegasys (pegylated Interferon alfa-2a)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 11/19/2025

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)
 - 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 ULN 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 $\leq 2,000$ IU/mL (HBeAg negative) or $\leq 20,000$ 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 ULN for at least 6 months
 4. Measurable HBV-DNA levels

- B. Chronic Hepatitis D (CHD) meeting criteria i and ii:
 - i. Documented elevated HDV-RNA levels.
 - ii. Documented elevated serum ALT levels.
- C. Off-label National Comprehensive Cancer Network (NCCN) guideline recommended diagnosis with a category of evidence and consensus of 1 or 2A (refer to **Appendix Table 1** for list of diagnoses)
 - i. Chronic myeloid leukemia
 - ii. Erdheim-Chester disease
 - 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
 - ix. Systemic mastocytosis
 - x. T-cell leukemia/lymphoma
- II. Treatment must be prescribed by or in consultation with a gastroenterologist, infectious disease specialist, hepatologist, or oncologist.
- III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.
- 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)
- Use in neonates or infants

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: An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

- * Evidence of significant histologic disease may include results such as moderate-to-severe inflammation (A2 or A3) and/or significant fibrosis ($\geq$ 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 Diagnosis³⁻¹⁶

Diagnosis	Recommendation
Chronic myeloid leukemia	• Treatment during pregnancy
Erdheim-Chester disease	• First line or subsequent disease
Essential thrombocythemia	• High risk disease and high-risk pregnancy
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 anaplastic large cell lymphoma (ALCL) with multifocal lesions: primary or relapsed/refractory disease
Polycythemia vera	• High risk disease and high-risk pregnancy
Systemic mastocytosis	• Symptomatic indolent systemic mastocytosis (ISM) or smoldering systemic mastocytosis (SSM) • Aggressive systemic mastocytosis

	Systemic mastocytosis with an associated hematologic neoplasm
T-Cell leukemia/lymphoma	Adult T-cell leukemia/lymphoma: acute or chronic smoldering (in combination with zidovudine)

*Recommendation may not be inclusive of all criteria required to approve treatment with Pegasys for diagnoses. Please refer to NCCN guidelines for the most up to date criteria.

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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.