Reference number(s)
Policy: 2139-A
Qsets: 5920-A, 6284-A

Specialty Guideline Management
Pegasys

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Pegasys	peginterferon alfa-2a

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.

FDA-approved Indications [1]

Chronic Hepatitis C (CHC)

- In combination therapy with other hepatitis C virus (HCV) drugs for adults with compensated liver disease. Pegasys monotherapy is indicated only if the patient has contraindication or significant intolerance to other HCV drugs.
- In combination with ribavirin for pediatric patients 5 years of age and older with compensated liver disease

Limitations of Use

- Pegasys alone or in combination with ribavirin without additional HCV antiviral drugs is not recommended for treatment of patients with CHC who previously failed therapy with an interferon-alfa.
- Pegasys is not recommended for treatment of patients with CHC who have had solid organ transplantation.

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Chronic Hepatitis B

- Treatment of adults with HBeAg-positive and HBeAg-negative chronic hepatitis B (CHB) infection who have compensated liver disease and evidence of viral replication and liver inflammation
- Treatment of non-cirrhotic pediatric patients 3 years of age and older with HBeAg-positive CHB and evidence of viral replication and elevations in serum alanine aminotransferase (ALT)

Compendial Uses[2,3]

- Chronic hepatitis E virus infection
- Myeloproliferative neoplasms (i.e., essential thrombocythemia, polycythemia vera, or symptomatic lower-risk myelofibrosis)
- Systemic mastocytosis
- Adult T-cell leukemia/lymphoma
- Mycosis fungoides/Sezary syndrome
- Primary cutaneous CD30+ T-cell lymphoproliferative disorders
- Hairy cell leukemia
- Erdheim-Chester disease
- Chronic myeloid leukemia

All other indications are considered experimental/investigational and not medically necessary.

Coverage Criteria

Chronic Hepatitis C Virus (HCV) Infection[1,4]

Refer to the SGM of requested regimen for the specific criteria for approval and approval durations.

Chronic Hepatitis B Virus (HBV) Infection (including hepatitis D virus [HDV] coinfection)[1,5]

Authorization of up to 48 weeks total may be granted for treatment of chronic HBV infection, including HDV coinfection.

Chronic Hepatitis E Virus (HEV) Infection in Liver Transplant Recipients[2,6,7]

Authorization of 12 months may be granted for treatment of chronic HEV infection when both of the following criteria are met:

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- Member is a liver transplant recipient.
- Member has had an inadequate response, intolerance, or contraindication to ribavirin.

Myeloproliferative Neoplasms[2]

Authorization of 12 months may be granted for treatment of myeloproliferative neoplasms (essential thrombocythemia, polycythemia vera, symptomatic lower-risk myelofibrosis).

Systemic Mastocytosis[2]

Authorization of 12 months may be granted for treatment of systemic mastocytosis.

Adult T-Cell Leukemia/Lymphoma[2]

Authorization of 12 months may be granted for treatment of adult T-cell leukemia/lymphoma.

Mycosis Fungoides/Sezary Syndrome[2]

Authorization of 12 months may be granted for treatment of mycosis fungoides/Sezary syndrome.

Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders[2]

Authorization of 12 months may be granted for treatment of primary cutaneous CD30+ T-cell lymphoproliferative disorders.

Hairy Cell Leukemia[2]

Authorization of 12 months may be granted for treatment of hairy cell leukemia.

Erdheim-Chester Disease[2]

Authorization of 12 months may be granted for treatment of Erdheim-Chester disease.

Chronic Myeloid Leukemia[2]

Authorization of 12 months may be granted for treatment of chronic myeloid leukemia in pregnancy.

Continuation of Therapy

Chronic HCV Infection, Chronic HBV Infection (including HDV coinfection), or Chronic HEV Infection in Liver Transplant Recipients

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All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

Myeloproliferative Neoplasm[2,8]

Authorization of 12 months may be granted if the member is experiencing benefit from therapy as evidenced by improvement in symptoms and/or disease markers (e.g., morphological response, reduction or stabilization in spleen size, improvement of thrombocytosis/leukocytosis).

Systemic mastocytosis[2,9]

Authorization of 12 months may be granted if the member is experiencing benefit from therapy as evidenced by improvement in symptoms and/or disease markers (e.g., reduction in serum and urine metabolites of mast cell activation, improvement in cutaneous lesions, skeletal disease, bone marrow mast cell burden).

All Other Indications

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for all other indications in the coverage criteria section, not previously listed, when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Pegasys [package insert]. South San Francisco, CA: Genentech, Inc; March 2021.
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4. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; December 2024.
5. Terrault NA, Lok ASF, McMahon BJ, et al. Update on prevention, diagnosis, and treatment of chronic hepatitis B: AASLD 2018 hepatitis B guidance. Hepatology. 2018;67(4):1560-1599. doi: 10.1002/hep.29800
6. European Association for the Study of the Liver. EASL clinical practice guidelines on hepatitis E virus infection. J Hepatol. 2018;68(6):1256-1271. doi: 10.1016/j.jhep.2018.03.005
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8. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology™ Myeloproliferative Neoplasms (Version 1.2025). http://www.nccn.org. Accessed March 15, 2025.
9. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology™ Systemic Mastocytosis (Version 1.2025). http://www.nccn.org. Accessed March 15, 2025.

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