# Pegasys (peginterferon alfa-2a)

## NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

## BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

## DESCRIPTION

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.

The criteria will require the use of the health plan's preferred agents for chronic Hepatitis C therapy (Epclusa, Harvoni, Mavyret, and Vosevi) before the use of other non-preferred agents, unless there are clinical circumstances that exclude the preferred agents, or the patient is currently receiving treatment with a non-preferred agent.

FDA-Approved Indications

1. Chronic Hepatitis C
   Pegasys, as part of a combination regimen with other hepatitis C virus (HCV) antiviral drugs, is indicated for the treatment of adults with chronic hepatitis C (CHC) with compensated liver disease. Pegasys in combination with ribavirin is indicated for treatment of pediatric patients 5 years of age and older with CHC and compensated liver disease.
   Pegasys monotherapy is only indicated for the treatment of patients with CHC with compensated liver disease if there are contraindications or significant intolerance to other HCV antiviral drugs.
2. Chronic Hepatitis B
   Pegasys is indicated for the treatment of adult patients with HBeAg-positive and HBeAg-negative chronic hepatitis B infection who have compensated liver disease and evidence of viral replication and liver inflammation. Pegasys is indicated for the treatment of HBeAg-positive CHB in non-cirrhotic pediatric patients 3 years of age and older with evidence of viral replication and elevations in serum alanine.

Compendial Uses

1. Myeloproliferative neoplasm (essential thrombocythemia, polycythemia vera, symptomatic lower-risk myelofibrosis)
2. Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders
3. Mycosis Fungoides/Sezary syndrome
4. Systemic mastocytosis
5. T-Cell lymphomas (adult T-Cell leukemia/lymphoma)
6. Hairy Cell Leukemia
7. Erdheim-Chester disease

## POLICY

Initial Criteria for Approval

*****The criteria will require the use of the health plan's preferred agents for chronic Hepatitis C therapy (Epclusa, Harvoni, Mavyret, and Vosevi) before the use of other non-preferred agents, unless there are clinical circumstances that exclude the preferred agents, or the patient is currently receiving treatment with a non-preferred agent.

**A. Chronic hepatitis C virus (HCV) infection**

1. Refer to the drug policy of requested regimen for the specific criteria for approval and approval durations.

**B. Chronic hepatitis B virus (HBV) infection (including HDV coinfection)**

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

**C. Myeloproliferative neoplasm**

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

**D. Systemic mastocytosis**

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

**E. Adult T-Cell Leukemia/Lymphomas**

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

**F. Mycosis Fungoides/Sezary Syndrome**

Authorization of 12 months may be granted for the treatment of Mycosis Fungoides/Sezary syndrome.

**G. Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders**

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

**H. Hairy cell leukemia**

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

**I. Erdheim-Chester disease**

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

Continuation of Therapy

**A. Myeloproliferative neoplasm**

Authorization of 12 months may be granted if the patient 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, etc.)

**B. Systemic mastocytosis**
Authorization of 12 months may be granted if the patient 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, etc.)

**C. All other indications**
Authorization of 12 months may be granted for continued treatment in patients requesting reauthorization for all other indications in Initial Criteria for Approval section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limit

- 180 mcg per week

Dispensing Limits

- A 28-day supply dispense limit applies to all targeted hepatitis C agents in order to better manage the therapy regimen.

## PROCEDURES AND BILLING CODES

***To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.***

- Code(s), if applicable

## REFERENCES


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- AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Last changes made August 27, 2020. Accessed March 4, 2021.
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- National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology™ Myeloproliferative Neoplasms (Version 1.2020). http://www.nccn.org. Accessed March 4, 2021.
- National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology™ Systemic Mastocytosis (Version 1.2020). http://www.nccn.org. Accessed March 4, 2021.


*Some content reprinted from CVSHealth

## POLICY HISTORY

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