CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Pegasys (peginterferon alfa-2a)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Pegasys is a pegylated recombinant human interferon alfa-2a initially approved by the FDA in 2002. Peginterferon alfa-2a is used alone or in combination with other medications to treat chronic hepatitis B and chronic hepatitis C, viral infections of the liver. It works by decreasing the amount of hepatitis virus in the body and helps the body's immune system fight the infection. Interferon-based treatment regimens are no longer recommended by the American Association for the Study of Liver Diseases/ Infectious Disease Society of America (AASLD-IDSA) HCV guidance due to the advent of safe and effective direct acting antivirals.

Pegasys (peginterferon alfa-2a) will be considered for coverage when the following criteria are met:

Hepatitis B

For **initial** authorization:

1. Member is an adult with chronic Hepatitis B (CHB) and compensated liver disease or a child (3 years of age or older) with non-cirrhotic HBeAg-positive CHB; AND
2. Medication must be prescribed by, or in consultation with, a board certified hepatologist, gastroenterologist or infectious disease specialist; AND
3. Member meets one of the following:
   a) Member has no cirrhosis, two elevated ALT lab values within the past 12 months (> 70 IU/L for men, > 50 IU/L for women) and HBV DNA levels > 20,000 IU/ml in HBeAg positive patients or >2,000 IU/mL in HBeAg negative patients; OR
   b) Member is an adult patient with cirrhosis and HBV DNA level > 2,000 IU/mL; AND
4. Member has tried and failed course of treatment with tenofovir (for ≥12 years of age) or entecavir (for ≥2 years of age); AND
5. Member does **not** have any of the following;
   a) Acute autoimmune hepatitis;
   b) Hepatic decompensation; AND
6. **Dosage allowed/Quantity limit:**
   Adults: 180 mcg (1.0 mL) subcutaneously once weekly.
   Pediatrics: BSA x 180 mcg/1.732 m^2 subcutaneously once weekly.
   Quantity Limit: 4 per 28 days

If all the above requirements are met, the medication will be approved for 48 weeks.

For **reauthorization**:

1. Chart notes must show improvement or stabilized signs and symptoms of disease, as demonstrated by an undetectable viral load.

If all the above requirements are met, the medication will be approved for an additional 12 months

Hepatitis C

For **initial** authorization:

1. Member is 5 years of age or older; AND
2. Medication must be prescribed by, or in consultation with, a board certified hepatologist, gastroenterologist, infectious disease specialist; AND
3. Member has a diagnosis of Chronic Hepatitis C (CHC) with compensated liver disease; AND
4. Member will use in combination with other hepatitis C virus drugs; Note: Monotherapy is permitted for adults only if the patient has a contraindication to other hepatitis C drugs; AND
5. Member does **not** have any of the following;
   a) Acute autoimmune hepatitis;
   b) HIV;
   c) Liver transplant;
   d) Hepatic decompensation; AND
6. **Dosage allowed/Quantity limit:**
   Adults: 180 mcg (1.0 mL) subcutaneously once weekly.
   Pediatrics: BSA x 180 mcg/1.732 m^2 subcutaneously once weekly.
   Quantity Limit: 4 per 28 days

If all the above requirements are met, the medication will be approved for 48 weeks.

For **reauthorization**:

1. Chart notes must show improvement or stabilized signs and symptoms of disease, as demonstrated by an undetectable viral load.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Pegasys (peginterferon alfa-2a) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
03/21/2018	New policy for Pegasys created. Coverage for adults for Hepatitis C was removed since no longer recommended by AASLD guidelines and since other more effective treatments are currently available. NCCN recommendations of off-label use added. CHB criteria revised.
06/21/2022	Transferred to new template. Updated References. Hepatitis B: Removed physician assistant or nurse practitioner and replaced with "in consultation with"; Clarified reauthorization criteria. Initial approval duration shortened to 48 weeks. Updated the ALT upper limit of normal per AASLD guidelines. Removed HIV exclusion from Hepatitis B indication. Hepatitis C: Added adult indication to hepatitis C per package insert. Added Pegasys is supposed to be used in combination with other Hepatitis C drugs. Clarified reauthorization criteria. Added exclusion criteria. Removed off-label Myeloproliferative Neoplasms indication

References:

1. Pegasys [package insert]. South San Francisco, CA: Genentech USA, Inc.; March 2021.
2. Update on Prevention, Diagnosis, and Treatment of Chronic Hepatitis B: AASLD 2018 Hepatitis B Guidance. PRACTICE GUIDANCE | HEPATOLOGY, VOL. 67, NO. 4, 2018.
3. AASLD/IDSA HCV guidance panel. Recommendations for testing, managing, and treating hepatitis C. Published: August 2020.

Effective date: 01/01/2023
Revised date: 06/21/2022