Pegasys (peginterferon alfa-2a)

**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.

**FDA-Approved Indications**
- 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 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.
- 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.

**Compendial Uses**
- Chronic myelogenous leukemia
- Giant cell tumor of the bone

All other indications are considered experimental/investigational and are not a covered benefit.

**POLICY**

**Required Documentation**
The following information is necessary to initiate the prior authorization review:
- Presence of viral load (HCV RNA) in the serum prior to treatment with the requested regimen
- Genotype and subtype (if applicable)
- Baseline or current viral load
- Laboratory testing for resistance-associated variants (if applicable)
- METAVIR fibrosis score (if applicable)
- Liver transplantation status
- Treatment plan including treatment regimen and duration
- Prior treatment regimen(s) and response
Prescriber specialty

Exclusions

- Decompensated cirrhosis (Child Turcotte Pugh Class B or C)

Note: When the requested drug is being used in a combination therapy regimen, exclusions to the other antiviral drugs also apply.

Initial Criteria for Approval

I. **Chronic hepatitis C virus infection, as monotherapy or in combination with ribavirin (RBV)**

- Authorization of up to 48 weeks total may be granted for members prescribed Pegasys as monotherapy or dual therapy in combination with RBV for the treatment of chronic hepatitis C virus infection.

II. **Chronic hepatitis C virus infection, in combination with Olysio and RBV**

- Authorization of up to 6 weeks total may be granted for initiation of therapy in members who are treatment-naive or failed prior treatment with PEG-IFN and RBV AND meet one of the following criteria:
  - Genotype 1a infection without the NS3 Q80K polymorphism
  - Genotype 1b infection
  - Genotype 4 infection

III. **Chronic hepatitis C virus infection, in combination with Sovaldi and RBV**

- Authorization of up to 12 weeks total (as applicable) may be granted for members prescribed PEG-IFN in combination with Sovaldi and RBV who meet the criteria for approval for the requested regimen. Refer to the Sovaldi SGM for the specific criteria for approval and approval durations.

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

- Authorization of up to 48 weeks total may be granted for members without cirrhosis who meet all of the following criteria:
  - HBsAg positive for at least 6 months prior to initiation of therapy
  - HBeAg-negative with serum HBV-DNA > 10^4 copies/mL or > 2000 IU/mL OR HBeAg-positive with serum HBV-DNA > 10^5 copies/mL or > 20,000 IU/mL
  - Persistent or intermittently elevated alanine aminotransferase (ALT) > 2x the upper limit of normal (ULN) OR liver biopsy showing chronic hepatitis with moderate to severe inflammation or significant fibrosis
- Authorization of up to 48 weeks total may be granted for members with cirrhosis who meet all of the following criteria:
  - HBsAg positive for at least 6 months prior to initiation of therapy
  - Serum HBV-DNA > 10^4 copies/mL or > 2000 IU/mL
- Authorization of up to 48 weeks total may be granted for members already receiving Pegasys therapy for hepatitis B.

V. **Chronic myelogenous leukemia**

- Authorization of 12 months may be granted for members prescribed Pegasys for the treatment of chronic myelogenous leukemia.

VI. **Giant cell tumor of the bone**

- Authorization of 12 months may be granted for members prescribed Pegasys for the treatment of giant cell tumor of the bone.
Continuation of Therapy

I. Chronic hepatitis C virus infection, genotype 1 or 4, in combination with Olysio and RBV

- Week 4 assessment
  - Authorization of up to 14 weeks total may be granted for members with HCV-RNA < 25 IU/mL at week 4 of treatment.

- Week 12 assessment
  - Authorization of up to 24 weeks total may be granted for members with HCV-RNA < 25 IU/mL at week 12 of treatment.
  - Treatment is complete at 24 weeks for members without a history of nonresponse to prior treatment with PEG-IFN and RBV and who have either of the following:
    - No HIV co-infection, or
    - HIV co-infection without cirrhosis

- Week 24 assessment
  - Authorization of up to 48 weeks total may be granted for members with HCV-RNA < 25 IU/mL at week 24 of treatment who have either of the following:
    - HIV co-infection with cirrhosis and without a history of nonresponse to prior treatment with PEG-IFN and RBV, or
    - Positive history of nonresponse to prior treatment with PEG-IFN and ribavirin (regardless of cirrhosis or HIV co-infection status).

Prior approval is required. Submit a prior approval/treatment request now.

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

Dosing Limits
The following dosing limits apply:
- 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

POLICY HISTORY

Policy #: 05.01.103
Policy Creation: January 2016
Reviewed: July 2016
Revised:
Current Effective Date: January 1, 2016