SPECIALTY GUIDELINE MANAGEMENT

PEGASYS (peginterferon alfa-2a)

POLICY

I. 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.

A. 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.

B. Compendial Uses
   1. Chronic myelogenous leukemia
   2. Myeloproliferative neoplasm (primary myelofibrosis and post-polycythemia vera or post-essential thrombocytopenia myelofibrosis)

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

II. INITIAL CRITERIA FOR APPROVAL

A. **Chronic hepatitis C virus (HCV) infection**
   Refer to the SGM 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. **Chronic myelogenous leukemia (CML)**
   Authorization of 12 months may be granted for the treatment of CML.

D. **Myeloproliferative neoplasm**
   Authorization of 12 months may be granted for the treatment of myeloproliferative neoplasm (primary myelofibrosis and post-polycythemia vera or post-essential thrombocytopenia myelofibrosis).

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

IV. REFERENCES

1. Pegasys [package insert]. South San Francisco, CA: Genentech, Inc; March 2015.
2. The NCCN Drugs & Biologics Compendium® © 2016 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed September 27, 2016.
3. Olysio [package insert]. Titusville, NJ: Janssen Products, LP; May 2016.
4. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; August 2015.
5. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Last changes made July 8, 2016. Accessed September 9, 2016.
6. Terrault NA, Bzowej NH, Chang KM, et al. AASLD guidelines for treatment of chronic hepatitis B. *Hepatology*. 2015;1-23.
7. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology™ Myeloproliferative Neoplasms (Version 1.2017). http://www.nccn.org. Accessed September 27, 2016.