Clinical Policy Title:	peginterferon alfa-2a, b
Policy Number:	RxA.248
Drug(s) Applied:	Pegasys®
Original Policy Date:	02/07/2020
Last Review Date:	08/19/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Chronic Hepatitis B Infection (must meet all):

1. Diagnosis of chronic hepatitis B virus infection;
2. Meets one of the following (a, b, or c):
   a. Two elevated ALT lab values within the past 12 months (e.g., 70 IU/L or greater for men, 50 IU/L or greater for women) and HBV DNA levels 20,000 IU/ml or greater; in HBeAg positive members or > 2,000 IU/mL in HBeAg negative members;
   b. Diagnosis of cirrhosis, HBV DNA level > 2,000 IU/mL, and Age ≥ 18 years;
   c. Liver biopsy shows moderate/severe necroinflammation (Grade 9-18) or significant fibrosis (Stage 3-4);
3. If age ≤ 17 years, member does not have cirrhosis.

Approval Duration

All lines of business (except Medicare): 12 months

B. NCCN-Recommended Off-Label Indications (off-label) (must meet all):

1. Diagnosis of one of the following (a, b, c, d, e, f, g, h, i, or j)):
   a. Myelofibrosis, low risk and symptomatic;
   b. Polycythemia vera;
   c. Essential thrombocythemia;
   d. Systemic mastocytosis (Osteopenia or osteoporosis with refractory bone pain and/or decreasing bone mineral density on bisphosphonate therapy);
   e. Hairy cell leukemia;
   f. Erdheim-Chester disease;
   g. Primary cutaneous CD30+ T-cell lymphoproliferative disorder as substitution for other interferon preparations;
   h. Adult T-cell leukemia or lymphoma as substitution for other interferon preparations;
   i. Mycosis fungoides or Sézary syndrome as substitution for other interferon preparations;
   j. Chronic myeloid leukemia, during pregnancy;
2. For hairy cell leukemia, used as a single agent following initial treatment with cladribine or pentaostatin
3. For Erdheim-Chester disease, used as a single agent for disease that is either symptomatic or relapsed/refractory.

Approval Duration

All lines of business (except Medicare): 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All lines of business (except Medicare): 12 months

References

1. Peginterferon alfa-2a/b. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/. Accessed September 4, 2024.
2. American Association for the Study of Liver Diseases/ Infectious Disease Society of America (AASLD-IDSA). HCV guidance: recommendations for testing, managing, and treating hepatitis C. Last updated October 24, 2022. Available at: https://www.hcvguidelines.org/https://www.hcvguidelines.org/. Accessed September 4, 2024.
3. Fried MW, Shiffman ML, Reddy KR, et al. Peginterferon alfa-2a plus ribavirin for chronic hepatitis C virus infection. N Engl J Med. 2002;347(13):975-982. Available at: https://www.nejm.org/doi/full/10.1056/NEJMoa020047. Accessed September 4, 2024.
4. Zeuzem S, Feinman SV, Rasenack J, et al. Peginterferon alfa-2a in patients with chronic hepatitis C. N Engl J Med. 2000;343(23):1666-1672. Available at: https://www.nejm.org/doi/full/10.1056/NEJM200012073432301. Accessed September 4, 2024.
5. Heathcote EJ, Shiffman ML, Cooksley WG, et al. Peginterferon alfa-2a in patients with chronic hepatitis C and cirrhosis. N Engl J Med. 2000;343(23):1673-1680. Available at: https://www.nejm.org/doi/full/10.1056/NEJM200012073432302. Accessed September 4, 2024.
6. National Comprehensive Cancer Network Guidelines. Chronic Myeloid Leukemia Version 1.2023. Available at https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf. Accessed September 4, 2024.
7. National Comprehensive Cancer Network Guidelines. Hairy Cell Leukemia Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hairy_cell.pdf. Accessed September 4, 2024.
8. National Comprehensive Cancer Network Guidelines. Erdheim-Chester Disease 1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/histiocytic_neoplasms.pdf. Accessed September 4, 2024.
9. National Comprehensive Cancer Network Guidelines. Myeloproliferative Neoplasms Version 3.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf. Accessed September 4, 2024.
10. National Comprehensive Cancer Network Guidelines. Primary Cutaneous Lymphomas Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf. Accessed September 4, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Policy title table was updated: Clinical Policy Title was updated to "peginterferon alfa-2a, b"; Drug(s) Applied was updated to "Pegasys®, PegIntron®, Sylatron™; Line of Business Policy Applies to was updated to "All". 2. Clinical policy was updated: Approval duration was updated for both Initial and Continued Approval Criteria;	08/01/2020	09/14/2020

Continued Approval was rephrased to "Currently receiving medication that has been authorized by RxAdvance….". 3. References were updated.		
Policy was reviewed: 1. Clinical Policy title was updated. 2. Initial Approval Criteria for approval updated along with the addition of other off label indications. 3. Initial duration of approval updated. 4. Continued Therapy criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance..." 5. References were reviewed and updated.	03/03/2021	06/10/2021
Policy was reviewed: 1. Initial Approval Criteria, I.E.3 to I.E.5: Updated to remove Pegintron – no longer recommended. 2. Initial Approval Criteria, I.G: Updated to include approval criteria for indication, Chronic Myeloid Leukemia (Off Label). 3. References were reviewed and updated.	01/11/2022	04/18/2022
Policy was reviewed: 1. Initial Approval Criteria, 1.B.3.a: Updated diagnostic criteria from Two elevated ALT lab values within the past 12 months (e.g., 70 IU/L or greater for men, 50 IU/L or greater for women) and HBV DNA levels 20,000 IU/ml or greater to Two elevated ALT lab values within the past 12 months (e.g., 70 IU/L or greater for men, 50 IU/L or greater for women) and HBV DNA levels 20,000 IU/ml or greater; in HBeAg positive members or > 2,000 IU/mL in HBeAg negative members; 2. Initial Approval Criteria, 1.B.3.b: Updated diagnostic criteria from Diagnosis of cirrhosis and member is ≥ 18 years of age to Diagnosis of cirrhosis, HBV DNA level > 2,000 IU/mL, and age ≥ 18 years. 3. Initial Approval Criteria off label	01/04/2023	04/13/2023

indications I.C, I.D, I.E, I.F and I.G are merged into one as I.C "NCCN-Recommended Off-Label Indications (off-label)". 4. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed PegIntron from policy.	05/15/2024	02/28/2024
Policy was removed: 1. Removed Pegintron from continued therapy criteria. 2. Remove age restriction. 3. Removed dose restriction. 4. Removed prescriber specialist restriction. 5. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 6. Updated approval duration language. 7. Removed continued therapy criteria for chronic hepatitis C. 8. References were reviewed and updated.	09/04/2024	09/13/2024