Clinical Policy: Peginterferon Alfa-2b (PegIntron, Sylatron)

Reference Number: PA.CP.PHAR.89
Effective Date: 01/18
Last Review Date: 09/17 Revision Log
Line of Business: Medicaid

Description
The following are alpha interferons requiring prior authorization: peginterferon alfa-2b (PegIntron®, Sylatron™).

FDA Approved Indication(s)
- Sylatron is indicated for the adjuvant treatment of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy.
- PegIntron is indicated for treatment of Chronic Hepatitis C (CHC) in patients with compensated liver disease.

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness ® that PegIntron and Sylatron are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Melanoma (must meet all)**:**
1. Request is for Sylatron;
2. Diagnosis of melanoma;
3. Member meets a or b:
   a. FDA approved use:
      i. Adjuvant treatment, initiated within 3 months of definitive surgery with complete lymphadenectomy;
      ii. Stage III disease with nodal involvement;
   b. Off-label NCCN recommended uses:
      i. Adjuvant treatment as a single agent for (a or b):
         a) Local, satellite and/or in-transit recurrence if no evidence of disease post-surgery;
         b) Following complete lymph node dissection and/or complete resection of nodal recurrence;
4. Request meets one of the following (a or b):
   a. Dose does not exceed initial dose of: 6 mcg/kg/week for 8 weeks, then 3 mcg/kg/week;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Myeloproliferative Neoplasms (off-label) (must meet all):

1. Request is for PegIntron or Sylatron;
2. Diagnosis of primary myelofibrosis or polycythemia vera or essential thrombocythemia;
3. Request meets one of the following (a or b):
   a. Dose does not exceed: 3 mcg/kg/week;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: Duration of request or 6 months (whichever is less)

C. Chronic Hepatitis C:

For PegIntron use in hepatitis C, see the following Pennsylvania Health and Wellness policies: PA.CP.PHAR.281 Sofosbuvir (Sovaldi) and PA.CP.PHAR.280 Simeprevir (Olysio).

D. Other diagnoses/indications

1. Refer to PA.CP.PMN.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Melanoma (must meet all)**:**

1. Currently receiving Sylatron via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member has not received ≥ 5 years of treatment;
3. Member is responding positively to therapy;
4. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 3 mcg/kg/week;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months (up to 5 years total)

B. Myeloproliferative Neoplasms (off-label) (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 3 mcg/kg/week;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: Duration of request or 12 months (whichever is less)

C. Chronic Hepatitis C:

For PegIntron use in hepatitis C, see the following Pennsylvania Health and Wellness policies: PA.CP.PHAR.281 Sofosbuvir (Sovaldi) and PA.CP.PHAR.280 Simeprevir (Olysio).

D. Other diagnoses/indications (1 or 2)**:**

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA.CP.PMN.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CHC: chronic hepatitis C
CML: chronic myelogenous leukemia
FDA: Food and Drug Administration
SC: subcutaneously

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
peginterferon alfa-2b (PegIntron, Sylatron)	primary myelofibrosis or post-polycythemia vera or post-essential myelofibrosis	Dose varies: 2-3 mcg/kg SC/week	Dose varies: 2-3 mcg/kg SC/week
peginterferon alfa-2b (Sylatron)	Melanoma	6 mcg/kg/week SC for 8 doses, followed by 3 mcg/kg/week SC for up to 5 years	6 mcg/kg/week SC for 8 doses, followed by 3 mcg/kg/week SC for up to 5 years

VI. Product Availability

Drug	Availability
peginterferon alfa-2b (PegIntron)	Vials (with diluent): 50 mcg/0.5 mL, 80 mcg/0.5 mL, 120 mcg/0.5 mL and 150 mcg/0.5 mL Redipen: 50 mcg/0.5 mL, 80 mcg/0.5 mL, 120 mcg/0.5 mL, and 150 mcg/0.5 mL
peginterferon alfa-2b (Sylatron)	Single-use vials: 296 mcg lyophilized powder, 444 mcg lyophilized powder, or 888 mcg lyophilized powder

VII. References

1. Sylatron Prescribing Information. Whitehouse Station, NJ: Merck and Co., Inc.; September 2015. Available at https://www.merck.com/product/usa/pi_circulars/s/sylatron/sylatron_pi.pdf. Accessed May 10, 2017.
2. PegIntron Prescribing Information. Whitehouse Station, NJ: Merck Sharp and Dohme Corp.; February 2016. Available at

https://www.merck.com/product/usa/pi_circulars/p/pegintron/pegintron_pi.pdf. Accessed May 10, 2017.
3. Peginterferon alpha-2b. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed May 10, 2017.
4. Jabbour E, Kantarjian H, Cortes J, et al. PEG-IFN-alpha-2b therapy in BCR-ABL-negative myeloproliferative disorders: final result of a phase 2 study. Cancer 2007; 100:2012-2018. Available at https://www.ncbi.nlm.nih.gov/pubmed/17849460. Accessed May 10, 2017.

Reviews, Revisions, and Approvals	Date	CPC Approval Date