peginterferon alfa-2B (Sylatron®)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO098

Description

Peginterferon alfa-2b (Sylatron) is a subcutaneous interferon which induces cellular activities related to binding specific cell-surface membrane receptors. These include suppression of cell proliferation, antiviral activity and immunomodulating effects.

Length of Authorization

- Initial: Eight weeks
- Renewal: 12 months, maximum of five years of therapy

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit
peginterferon-alfa 2b (Sylatron)	200 mcg subcutaneous powder for solution	Adjuvant treatment of melanoma with microscopic or gross nodal involvement	4 vials/ 28 days
	300 mcg subcutaneous powder for solution		
	600 mcg subcutaneous powder for solution		

Initial Evaluation

I. Peginterferon alfa-2b (Sylatron) may be considered medically necessary when the following criteria below are met:
   A. Member is 18 years of age or older; **AND**
   B. Medication is prescribed by, or in consultation with an oncologist; **AND**
   C. A diagnosis of **melanoma** when the following are met:
      1. The member has stage III disease; **AND**
      2. The member has microscopic or gross nodal involvement; **AND**
      3. The member has had definitive surgical resection including complete lymphadenectomy within the past 84 days (12 weeks); **AND**
      4. Peginterferon alfa-2b is prescribed as adjuvant treatment; **AND**

5. The prescribed dose does not exceed 6 mcg/kg per week for the first eight weeks, then 3 mcg/kg per week thereafter; **AND**
6. Attestation from the provider that the member does **not** have any of the following:
    i. Hepatic decompensation (Child-Pugh Score >6, class B and C)
    ii. Autoimmune hepatitis
    iii. Depression or other neuropsychiatric disorders

II. Peginterferon-alfa 2b (Sylatron) is considered investigational when used for all other conditions, including but not limited to:
    A. Hepatitis C
    B. Cholangiocarcinoma
    C. Hematological malignancies
    D. Solid tumors and malignancies outside of melanoma

Renewal Evaluation

I. Member has not been established on therapy by the use of free samples, manufacturer coupons, or otherwise; **AND**
II. Member has received a previous prior authorization approval for this agent; **AND**
III. The medication is prescribed by or in consultation with an oncologist; **AND**
IV. Member has experienced response to treatment, such as stabilization of disease, decrease in disease spread, regression of disease; **AND**
V. The prescribed dose does not exceed 3 mcg/kg after the first eight weeks of therapy; **AND**
VI. Attestation from the provider that the member does **not** have any of the following:
- Hepatic decompensation (Child-Pugh Score >6, class B and C)
- Autoimmune hepatitis
- Depression or other neuropsychiatric disorders

Supporting Evidence

I. Peginterfeon-alfa 2b (Sylatron) was evaluated in an open-label, randomized study of 1256 subjects with surgically resected stage III melanoma within 84 days (12 weeks) of regional lymph node dissection. The dose administered was 6 mcg/kg per week for eight weeks on average. Less than 1% received this dose for longer than nine weeks; thus, safety and efficacy for this dose for more than eight weeks is not FDA-approved and has not been sufficiently evaluated for safety and or efficacy.

II. Subjects were randomized to observation or peginterferon-alfa 2b (Sylatron) for up to five years. The primary outcome was relapse-free survival (RFS) or death from any cause, with overall survival (OS) as the secondary outcome. The RFS duration for peginterferon-alfa 2b (Sylatron) was 34.8 months versus 25.5 months for the observation arm. Safety and efficacy past five years of therapy has not been established, and OS benefits have not been established.

III. Peginterferon-alfa 2b (Sylatron) has a Black Box Warning for neuropsychiatric disorders, and may cause or aggravate severe depression or other psychiatric adverse events. Members with these conditions should only be started on therapy if the benefit outweighs the risks and should be monitored closely. Resolution of symptoms does not always occur upon discontinuation. Additionally, peginterferon-alfa 2b (Sylatron) is contraindicated in autoimmune hepatitis and those with hepatic decompensation.

IV. Vials of peginterferon-alfa 2b (Sylatron) are dose priced; therefore, vial size should be chosen to provide the appropriate dose and minimize waste.

V. As of November 2019, National Comprehensive Cancer Network treatment guidelines for cutaneous melanoma did not have recommendations for peginterferon-alfa 2b (Sylatron) in the setting of melanoma.

Investigational or Not Medically Necessary Uses

I. Peginterferon-alfa 2b (Sylatron) is not FDA-approved and has not been sufficiently evaluated for safety and/or efficacy in the following settings:
   A. Hepatitis C
   B. Cholangiocarcinoma
   C. Hematological malignancies
   D. Solid tumors and malignancies outside of melanoma

References

1. Sylatron [Prescribing Information]. Merck Sharp & Dohme Corp. Whitehouse Station, NJ. 2011.
2. NCCN Clinical Practice Guidelines in Oncology Cutaneous Melanoma. V3.2019. National Comprehensive Cancer Network. October 22, 2019. Available at: https://www.nccn.org/professionals/physician_gls/default.aspx#melanoma.

Policy Implementation/Update:

Date Created	December 2012
Date Effective	January 2013
Last Updated	November 2019
Last Reviewed	11/2019

Action and Summary of Changes	Date
Prior authorization criteria transitioned to policy format. Criteria updated to include age edit, stage of disease, place in therapy, maximum dose. Renewal criteria updated to current format and language, added specialist requirement, contraindications, dose check. Change of initial duration of approval, change to maximum coverage of five years.	11/2019