Sylatron

Description

Sylatron (peginterferon alfa-2b)

Background

Sylatron (peginterferon alfa-2b) is an alfa interferon, a cytokine whose mechanism of action in patients with melanoma is unknown.\(^1\) Sylatron was approved by the FDA on March 29, 2011.\(^2\)

Peginterferon alfa-2b is also sold under the brand name Peg-Intron.\(^4\) It is possible that some prescribers might attempt to use Sylatron for any of the uses for which Peg-Intron might be used, both labeled (e.g., hepatitis C)\(^3\) and off-label (including renal cell carcinoma, chronic myelogenous leukemia, condyloma acuminatum in patients with treatment-resistant-HIV infection, and essential thrombocythemia).\(^5\) Sylatron and Peg-Intron are dosed differently and are available in different dosages. Peg-Intron is available in 50, 80, 120, and 150 mcg/0.5 mL single-use vials, dosed by body weight 1 mcg/kg/week SQ for up to 48 weeks.\(^4\) Sylatron is available in 296, 444, and 888 mcg single-use powder vials, dosed by body weight at 6 mcg/kg/wk SQ for 8 doses, followed by 3 mcg/kg/wk SQ for up to 5 years.\(^1\)

NCCN Drugs & Biologics Compendium recommends Peginterferon alfa-2b as the primary treatment as a single agent for newly diagnosed CML, defined as Philadelphia chromosome-positive AND/OR BCR-ABL-positive, in rare patients unable to tolerate imatinib, dasatinib, or nilotinib or are post transplant without remission or with relapse.\(^6,7\)
Regulatory Status

FDA-approved indication: Sylatron is an alpha interferon indicated for the adjuvant treatment of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy.¹

Sylatron has the following black-box warning regarding depression and other neuropsychiatric disorders: “The risk of serious depression, with suicidal ideation and completed suicides, and other serious neuropsychiatric disorders are increased with alpha interferons, including Sylatron. Permanently discontinue Sylatron in patients with persistently severe or worsening signs or symptoms of depression, psychosis, or encephalopathy. These disorders may not resolve after stopping Sylatron.”

Sylatron prescribing information contains warnings about adverse reactions including: neuropsychiatric (including suicide, suicidal and homicidal ideation, depression, and an increased risk of relapse of recovering drug addicts, aggressive behavior, psychoses, hallucinations, bipolar disorders, mania, and encephalopathy), cardiovascular (including myocardial infarction, bundle-branch block, ventricular tachycardia, supraventricular arrhythmia, hypotension, cardiomyopathy, and angina pectoris), ocular (including a decrease in visual acuity or blindness due to retinopathy, macular edema, retinal artery or vein thrombosis, retinal hemorrhages and cotton wool spots, optic neuritis, papilledema, and serous retinal detachment), hepatic (Sylatron increases the risk of hepatic decompensation and death in patients with cirrhosis), and endocrinopathy (hypothyroidism, hyperthyroidism, and diabetes mellitus).¹

Sylatron is contraindicated in patients with a history of anaphylaxis reaction to peginterferon alfa-2b or interferon alfa-2b, autoimmune hepatitis, or hepatic decompensation (Child-Pugh score >6 [class B and C]).

Related policies
Alferon N, Intron A

Policy
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.
Prior-Approval Requirements

**Diagnosis**

Patient must have **ONE** of the following diagnoses

1. Melanoma
   
   **AND ALL** of the following:
   
   A. Gross or microscopic nodal involvement, and
   
   B. Had surgical resection including complete lymphadenectomy, and
   
   C. Request is being made within 84 days (12 weeks) of surgical resection

2. Chronic myelogenous leukemia (CML) in the first chronic phase that are Philadelphia chromosome-positive **AND/OR** BCR-ABL positive
   
   **AND**
   
   Unable to tolerate tyrosine kinase inhibitors e.g. Gleevec (imatinib), Sprycel (dasatinib) or Tasigna (nilotinib)
   
   **OR**
   
   Is post transplant without remission or with relapse

**AND NONE** of the following:

1. Autoimmune hepatitis
2. Decompensated hepatic disease
3. Uncontrolled major depression – patient must be monitored for signs and symptoms of depression and other psychiatric symptoms during treatment
Prior – Approval Renewal Requirements

Patient must have ALL of the following
1. Is currently receiving Sylatron therapy
2. Is being monitored for signs and symptoms of depression and other psychiatric disorders

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval Renewal Limits

Duration 12 months per renewal, for up to 5 years total treatment time

Rationale

Summary
Sylatron is an alpha interferon indicated for the adjuvant treatment of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy.

NCCN Drugs & Biologics Compendium recommends Peginterferon alfa-2b as the primary treatment as a single agent for newly diagnosed CML, defined as Philadelphia chromosome-positive AND/OR BCR-ABL-positive, in rare patients unable to tolerate imatinib, dasatinib, or nilotinib or are post transplant without remission or with relapse.

Sylatron has the following black-box warning regarding depression and other neuropsychiatric disorders: “The risk of serious depression, with suicidal ideation and completed suicides, and other serious neuropsychiatric disorders are increased with alpha interferons, including Sylatron. Permanently discontinue Sylatron in patients with persistently severe or worsening signs or symptoms of depression, psychosis, or encephalopathy. These disorders may not resolve after stopping Sylatron.”
Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Sylatron while maintaining optimal therapeutic outcomes.

References


Policy History

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<td>December 2011</td>
<td>New Policy</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Therapeutics Committee on December 6, 2012 and is effective January 1, 2013.

Signature on File

James A. Ferrendelli, M.D.