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. Sylatron is used to prevent malignant melanoma from coming back after it has been removed by surgery. Sylatron should be started within 84 days of surgery on the melanoma (1-3).

Regulatory Status
FDA-approved indication: 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 (1).

Sylatron has a boxed warning regarding depression and other neuropsychiatric disorders. This warning addresses the risks of serious depression, with suicidal ideation and completed suicides, and other serious neuropsychiatric disorders. It is important to 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 (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]) (1).
Policy

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

Sylatron may be considered medially necessary in patients are 18 years of age or older with a confirmed diagnosis of melanoma and if the conditions indicated below are met.

Sylatron is considered investigational in patients that are below 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:
Melanoma
   a. Gross or microscopic nodal involvement, and
   b. Had surgical resection including complete lymphadenectomy
   c. Request is being made within 84 days (12 weeks) of surgical resection

AND NONE of the following:
   a. Autoimmune hepatitis
   b. Decompensated hepatic disease
   c. Uncontrolled major depression – patient must be monitored for signs and symptoms of depression and other psychiatric symptoms during treatment

Prior – Approval Renewal Requirements

Age 18 years of age and older

Diagnosis
Patient must have the following:
  Melanoma

AND ALL of the following:
  a. Is currently receiving Sylatron therapy
  b. 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 used to prevent malignant melanoma from coming back after it has been removed by surgery. Sylatron should be started within 84 days of surgery on the melanoma. Sylatron has a boxed warning regarding depression and other neuropsychiatric disorders (1).

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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<tr>
<th>Date</th>
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<tbody>
<tr>
<td>December 2011</td>
<td>New Policy</td>
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<tr>
<td>December 2012</td>
<td>Annual editorial review and reference update</td>
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<td>March 2014</td>
<td>Annual editorial review and reference update</td>
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Section: Prescription Drugs  Effective Date: July 1, 2019
Subsection: Antineoplastic Agents  Original Policy Date: December 7, 2011
Subject: Sylatron  Page: 4 of 4

December 2014  Annual editorial review and reference update
December 2015  Annual editorial review and reference update
               Removed Chronic myelogenous leukemia (CML) diagnosis per PMPC
March 2016     Annual editorial review and reference update
               Policy number change from 5.04.11 to 5.21.11
June 2016      Annual editorial review and reference update
               Addition of an indication: Giant cell tumor of the bone
June 2017      Annual editorial review and reference update
               Addition of age requirement to the renewal criteria
June 2018      Annual editorial review and reference update
               Removal of Giant Cell Tumor of Bone diagnosis from initiation and renewal
               criteria
June 2019      Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on
June 20, 2019 and is effective on July 1, 2019.