



**POLICY:** Oncology – Sylatron™ (peginterferon alfa-2b injection for subcutaneous use – Merck)

**DATE REVIEWED:** 12/18/2019

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### OVERVIEW

Sylatron, a pegylated interferon alfa-2b product, is indicated for adjuvant treatment of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy.<sup>1</sup>

### Guidelines

The National Comprehensive Cancer Network (NCCN) cutaneous melanoma (Version 3.2019 – October 22, 2019) clinical practice guidelines no longer recommend Sylatron for the treatment of melanoma.<sup>2</sup>

The NCCN systemic mastocytosis (Version 2.2019 – September 20, 2018) clinical practice guidelines recommend Sylatron alone or in combination with prednisone for the treatment of aggressive systemic mastocytosis and systemic mastocytosis with an associated hematologic neoplasm when the systemic mastocytosis component needs more immediate treatment.<sup>3,4</sup> In addition, Sylatron is recommended osteopenia/osteoporosis in patients with refractory bone pain and/or worsening bone mineral density on bisphosphonate therapy.

The NCCN myeloproliferative neoplasms (Version 3.2019 – September 4, 2019) clinical practice guidelines recommend Sylatron for the treatment of symptomatic low-risk myelofibrosis, polycythemia vera, and essential thrombocythemia.<sup>4,5</sup>

### POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of Sylatron. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist).

Because of the specialized skills required for evaluation and diagnosis of patients treated with Sylatron as well as the monitoring required for adverse events and long-term efficacy, approval requires Sylatron to be prescribed by or in consultation with a physician who specializes in the condition being treated.

### RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Sylatron is recommended in those who meet the following criteria:

### FDA-Approved Indications

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1. **Melanoma.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
    - A) The patient has microscopic or gross nodal involvement; AND
    - B) The patient had complete lymphadenectomy within the past 84 days; AND
    - C) Sylatron will be prescribed by or in consultation with an oncologist.
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**Dosing.** Approve the following dosing regimen: Each individual dose must not exceed 6 mcg/kg given subcutaneously no more frequently than once weekly.<sup>1</sup>

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### Other Uses with Supportive Evidence

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**2. Systemic Mastocytosis.** Approve for 1 year if the patient meets the following (A and B):

- A) The patient has one of the following (i, ii, or iii):
- i. Aggressive systemic mastocytosis; OR
  - ii. Systemic mastocytosis with an associated hematologic malignancy; OR
  - iii. Osteopenia/osteoporosis with refractory bone pain and/or decreasing bone mineral density on bisphosphonate therapy; AND
- B) Sylatron is prescribed by or in consultation with an oncologist.

**Dosing.** Approve the following dosing regimen: Each individual dose must not exceed 6 mcg/kg given subcutaneously no more frequently than once weekly.<sup>1</sup>

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**3. Myeloproliferative Neoplasms.** Approve for 1 year if the patient meets the following (A and B):

- A) The patient has one of the following (i, ii, or iii):
- i. Symptomatic low-risk myelofibrosis; OR
  - ii. Polycythemia vera; OR
  - iii. Essential thrombocythemia; AND
- B) Sylatron is prescribed by or in consultation with an oncologist.

**Dosing.** Approve the following dosing regimen: Each individual dose must not exceed 6 mcg/kg given subcutaneously no more frequently than once weekly.<sup>1,6</sup>

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### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Sylatron has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

### REFERENCES

1. Sylatron™ injection for subcutaneous use [prescribing information]. Whitehouse Station, NJ: Merck; August 2019.
2. The NCCN Cutaneous Melanoma Clinical Practice Guidelines (Version 3.2019 – October 22, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed November 19, 2019.
3. The NCCN Systemic Mastocytosis Clinical Practice Guidelines (Version 2.2019 – September 20, 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed November 19, 2019.
4. The NCCN Drugs and Biologics Compendium. © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on November 19, 2019. Search term: Sylatron.
5. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines (Version 3.2019 – September 4, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed November 19, 2019.
6. Jabbour E, Kantarjian H, Cortes J, et al. PEG-IFN- $\alpha$ -2b therapy in BCL-ABL-negative myeloproliferative disorders. Final results of a Phase 2 study. *Cancer*. 2007;110:2012-2018.

**HISTORY**

<b>Type of Revision</b>	<b>Summary of Changes</b>	<b>Date Reviewed</b>
New Policy	--	12/18/2019