VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Sylatron Utilization Management Medical Policy
- Sylatron™ (peginterferon alfa-2b injection for subcutaneous use – Merck)

REVIEW DATE: 12/16/2020

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.[1]

Guidelines

National Comprehensive Cancer Network (NCCN) clinical practice guidelines:
- The NCCN **cutaneous melanoma** (version 1.2021 – November 25, 2020) clinical practice guidelines no longer recommend Sylatron for the treatment of melanoma.[2]
- The NCCN **myeloproliferative neoplasms** (version 1.2020 – May 21, 2020) clinical practice guidelines no longer recommend Sylatron for the treatment of myelodysplastic neoplasms.[4]
- The NCCN **systemic mastocytosis** (version 1.2020 – May 21, 2020) clinical practice guidelines no longer recommend Sylatron for the treatment of systemic mastocytosis.[3]

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 indications. 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). All approvals are provided for the duration noted below.

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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Melanoma.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
   - **A)** Patient has microscopic or gross nodal involvement; AND
   - **B)** Patient had complete lymphadenectomy within the past 84 days; AND
   - **C)** Sylatron will be 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.[1]

Other Uses with Supportive Evidence

---

2. Myeloproliferative Neoplasms. Approve for 1 year if the patient meets the following (A and B):
- **A)** 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.[1,5]

---

3. Systemic Mastocytosis. Approve for 1 year if the patient meets the following (A and B):
- **A)** 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.[1]

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Sylatron is not recommended in the following situations:

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 1.2021 – November 25, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed December 10, 2020.
3. The NCCN Systemic Mastocytosis Clinical Practice Guidelines (Version 1.2020 – May 21, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed December 10, 2020.
4. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines (Version 1.2020 – May 21, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed December 10, 2020.
5. Jabbour E, Kantarjian H, Cortes J, et al. PEG-IFN-α-2b therapy in BCL-ABL-negative myeloproliferative disorders. Final results of a Phase 2 study. *Cancer*. 2007;110:2012-2018.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	12/18/2019
Annual Revision	No criteria changes.	12/16/2020