Sylatron® (Peginterferon alfa-2b)
(Subcutaneous)

Document Number: IC-0189

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Date of Origin: 04/15/2014
Dates Reviewed: 02/2015, 01/2016, 1/2017, 01/2018, 01/2019

I. Length of Authorization

Coverage is provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Sylatron 200 mcg: 4 syringes per 28 days
- Sylatron 300 mcg: 4 syringes per 28 days
- Sylatron 600 mcg: 4 syringes per 28 days

B. Max Units (per dose and over time) [Medical Benefit]:

- N/A

III. Initial Approval Criteria

- Patient is at least 18 years or older; **AND**

Coverage is provided in the following condition(s):

Melanoma†

- Used as single agent adjuvant therapy; **AND**
- Patient has microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy

Myeloproliferative Neoplasms ‡

- Myelofibrosis
  - Patient has symptomatic, low-risk disease
- Polycythemia Vera
  - Patient has high-risk or symptomatic low-risk disease, with indications for therapy; **OR**
  - Patient had a loss or inadequate response to hydroxyurea or interferon therapy and is peginterferon alfa-2b naïve

- Essential Thrombocythemia
    - Patient has very-low, low, intermediate or high-risk disease, with indications for therapy; **OR**
    - Patient had a loss or inadequate response to hydroxyurea, interferon therapy or anagrelide and is peginterferon alfa-2b naïve

Systemic Mastocytosis ‡

- Used as single agent or with prednisone for the treatment of aggressive disease or systemic mastocytosis associated with a hematologic neoplasm (SM-AHN), when the SM component requires more immediate treatment; **OR**
- Used for osteopenia/osteoporosis in patients with refractory bone pain and/or worsening bone mineral density on bisphosphonate therapy.

† FDA-labeled indication(s); ‡ Compendia approved indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria identified in Section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: persistent or worsening severe neuropsychiatric disorders, grade 4 non-hematologic toxicity, new or worsening retinopathy, new onset of ventricular arrhythmia, cardiovascular decompensation, hepatic failure, endocrinopathies (new onset or worsening of hypothyroidism, hyperthyroidism, and diabetes mellitus), etc.; **AND**
- Total length of therapy does not exceed 5 years

V. Dosage/Administration

Indication	Dose
All Indications	6 mcg/kg/week subcutaneously for 8 doses, followed by 3 mcg/kg/week subcutaneously for up to 5 years

VI. Billing Code/Availability Information

HCPCS:

- J9999 – Not otherwise classified, antineoplastic drugs
- C9399 – Unclassified drugs or biologicals (Hospital Outpatient Use ONLY)

NDC:

- Sylatron 200 mcg: 00085-4347-xx

- Sylatron 300 mcg: 00085-4348-xx
- Sylatron 600 mcg: 00085-4349-xx

VII. References

1. Sylatron [package insert]. Whitehouse Station, NJ; Merck & Co., Inc., May 2018. Accessed December 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) peginterferon alfa-2b. National Comprehensive Cancer Network, 2017. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed December 2018.
3. Lehman T, Beyeler C, Lammle B, et al. Severe osteoporosis due to systemic mast cell disease: successful treatment with interferon alpha-2B. Br J Rheumatol 1996;35:898-900.
4. Weide R, Ehlenz K, Lorenz W, et al. Successful treatment of osteoporosis in systemic mastocytosis with interferon alpha-2b. Ann Hematol 1996;72:41-43.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C43.0	Malignant melanoma of lip
C43.10	Malignant melanoma of unspecified eyelid, including canthus
C43.11	Malignant melanoma of right eyelid, including canthus
C43.12	Malignant melanoma of left eyelid, including canthus
C43.20	Malignant melanoma of unspecified ear and external auricular canal
C43.21	Malignant melanoma of right ear and external auricular canal
C43.22	Malignant melanoma of left ear and external auricular canal
C43.30	Malignant melanoma of unspecified part of face
C43.31	Malignant melanoma of nose
C43.39	Malignant melanoma of other parts of face
C43.4	Malignant melanoma of scalp and neck
C43.51	Malignant melanoma of anal skin
C43.52	Malignant melanoma of skin of breast
C43.59	Malignant melanoma of other part of trunk
C43.60	Malignant melanoma of unspecified upper limb, including shoulder
C43.61	Malignant melanoma of right upper limb, including shoulder
C43.62	Malignant melanoma of left upper limb, including shoulder

ICD-10	ICD-10 Description
C43.70	Malignant melanoma of unspecified lower limb, including hip
C43.71	Malignant melanoma of right lower limb, including hip
C43.72	Malignant melanoma of left lower limb, including hip
C43.8	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified
C80.0	Disseminated malignant neoplasm, unspecified
C80.1	Malignant (primary) neoplasm, unspecified
C94.40	Acute panmyelosis with myelofibrosis not having achieved remission
C94.41	Acute panmyelosis with myelofibrosis in remission
C94.42	Acute panmyelosis with myelofibrosis in relapse
C94.6	Myelodysplastic disease, not classified
C96.20	Malignant mast cell neoplasm, unspecified
C96.21	Aggressive systemic mastocytosis
C96.22	Mast cell sarcoma
C96.29	Other malignant mast cell neoplasm
D45	Polycythemia vera
D47.02	Systemic mastocytosis
D47.1	Chronic myeloproliferative disease
D47.3	Essential (hemorrhagic) thrombocythemia
D47.4	Osteomyelofibrosis
D75.81	Myelofibrosis
Z85.820	Personal history of malignant melanoma of skin

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA,HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC