

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

Sylatron (peginterferon alfa-2b)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Sylatron (peginterferon alfa-2b)

APPROVAL CRITERIA

Requests for Sylatron (peginterferon alfa-2b) may be approved if the following criteria are met:

- I. Individual has a diagnosis of Melanoma with microscopic or gross nodal involvement; **AND**
 - A. Treatment is initiated within 84 days after definitive surgical resection including complete lymphadenectomy; **AND**
 - B. Sylatron is used as adjuvant treatment;

OR

- II. Individual has a diagnosis of Myeloproliferative Neoplasms; **AND**
 - A. Sylatron is being used for:
 1. Symptomatic, low risk myelofibrosis; **OR**
 2. Symptomatic low-risk or high risk polycythemia vera; **OR**
 3. Polycythemia vera and individual has an inadequate response to hydroxyurea or interferon therapy **AND** is peginterferon alfa-2b naïve;
 4. Very-low, low, intermediate, or high risk essential thrombocythemia; **OR**
 5. Essential thrombocythemia and individual has an inadequate response to hydroxyurea, interferon therapy, or anagrelide, **AND** is peginterferon alfa-2b naïve;

OR

- III. Individual has a diagnosis of aggressive Systemic Mastocytosis or systemic mastocytosis associated hematologic neoplasm (SM-AHN) (NCCN 2A).

Requests for Sylatron (peginterferon alfa-2b) may not be approved when the above criteria are not met and for all other indications.

Note:

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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Sylatron (peginterferon alfa-2b) has a black box warning for risk of 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. Therapy should be permanently discontinued in individuals with persistently severe or worsening signs or symptoms of depression, psychosis, or encephalopathy. These disorders may not resolve after stopping Sylatron.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: September 30, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on September 30, 2019.
 - a. Myeloproliferative Neoplasms. V3.2019. Revised September 4, 2019.
 - b. Systemic Mastocytosis. V2.2019. Revised September 20, 2018.

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