

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

\*FHK- Florida Healthy Kids

## 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 (NCCN 2A); **OR**
    2. Symptomatic low-risk or high risk polycythemia vera (NCCN 2A); **OR**
    3. Polycythemia vera and individual has an inadequate response to hydroxyurea or interferon therapy AND is peginterferon alfa-2b naïve (NCCN 2A);
    4. Very-low, low, intermediate, or high risk essential thrombocythemia (NCCN 2A); **OR**
    5. Essential thrombocythemia and individual has an inadequate response to hydroxyurea, interferon therapy, or anagrelide, AND is peginterferon alfa-2b naïve (NCCN 2A);

#### **OR**

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

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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**Note:** 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.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

**Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. 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: October 2018.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. The NCCN Drugs & Biologics Compendium (NCCN Compendium™) © 2018 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically.

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