Commercial/Healthcare Exchange PA Criteria
Effective: August 2016

Prior Authorization: Sylatron

Products Affected: Sylatron (peginterferon alfa-2b) powder for injection

Medication Description:
Sylatron is an alpha interferon indicated for the adjuvant treatment of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy. Peginterferon alfa-2b is a pleiotropic cytokine; the mechanism by which it exerts its effects in patients with melanoma is unknown. Sylatron has a Boxed Warning. The risk of serious depression, with suicidal ideation and completed suicides, and other serious neuropsychiatric disorders are increased with the use of alpha interferons, including Sylatron. Sylatron should be permanently discontinued in patients with persistently severe or worsening signs or symptoms of depression, psychosis, or encephalopathy. These disorders may not resolve after discontinuation of Sylatron.

Covered Uses: Adjuvant treatment of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy.

Exclusion Criteria:
1. History of anaphylaxis to peginterferon alfa-2b or interferon alfa-2b
2. Autoimmune hepatitis
3. Hepatic decompensation (Child-Pugh score >6 [class B and C])

Required Medical Information:
1. Diagnosis
2. Surgical resection/lymphadenectomy status
3. Previous therapies tried

Age Restrictions: 18 years of age or older

Prescriber Restrictions: Prescribed by, or in consultation with, an oncologist.

Coverage Duration:
12 months
Note: for malignant melanoma total length of therapy does not exceed 5 years

Other Criteria:
Approve if the patient meets the following criteria:
   a. Patient has a diagnosis of melanoma with microscopic or gross nodal involvement; AND
   b. Patient is within 84 days of definitive surgical resection including complete lymphadenectomy

References:
1. Sylatron [prescribing information]. Whitehouse Station, NJ: Merck & Co, Inc; September 2015.

2. The NCCN Clinical Practice Guidelines in Oncology, Melanoma Version 3.2016. © 2015 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on August 17, 2016.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	08/22/2016
2	Update	Update policy to FDA label	Exclusion Criteria	12/11/2019
3	CCI to adopt EH policy	Alignment with enterprise	ALL	12/12/2019