



Prior Authorization Approval Criteria

Sylatron (peginterferon alfa-2b)

Generic name:	Peginterferon alfa-2b
Brand name:	Sylatron
Medication class:	Interferon
FDA-approved uses:	Adjuvant treatment of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy
Available dosage forms:	296mcg single-use vial 444mcg single-use vial 888mcg single-use vial
Usual dose:	Induction: 6mcg/kg/week subcutaneously for 8 doses Maintenance: 3mcg/kg/week subcutaneously
Approximate monthly cost: (based on AWP 2011)(70kg)	Induction: \$6,400 Maintenance: \$4,300
Duration of therapy:	Treatment for up to 5 years

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Clinically diagnosis of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy
- ECOG PS \leq 1

Criteria for continuation of therapy:

- ECOG PS \leq 1
- Absolute Neutrophil Count $>$ $0.5 \times 10^9/L$
- Platelet count $>$ $50 \times 10^9/L$
- Non-hematologic toxicity has completely resolved or improved to Grade 1
- Patient is obtaining clinical benefit from the use of this medication

Monitoring:

- Depression
- Cardiovascular adverse reactions
- Retinopathy
- Hepatic Failure
- Endocrinopathies

Contraindication:

- Known hypersensitivity reactions to peginterferon alfa-2b or interferon alfa-2b
- Autoimmune hepatitis
- Hepatic decompensation

Not approved if:

- Does not meet the above stated criteria
- Patient has any contraindications to the use of PEG-Intron

Special considerations:

- Pharmacy benefit if patient self-administers.
- Median time to relapse was 34.8 months versus 25.5 months on placebo
- Overall survival is not affected by treatment
- Designed for patient administration

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 12/14/11