

Title: *peginterferon alfa-2b (Sylatron)*

Origination: 08/24/11	Revised:	Annual Review: 12/15/11
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Medication Summary

- Sylatron (peginterferon alfa-2b) is a covalent conjugate of recombinant interferon alfa-2b with monomethoxy polyethylene glycol (PEG) that is indicated for the treatment of chronic hepatitis C and for the adjuvant treatment of melanoma.
- 'Pegylated' interferon alfa-2b has a longer half-life than interferon alfa-2b. This prevents viral replication between doses.
- Sylatron (peginterferon alfa-2b) has significantly higher sustained virologic response rates than interferon alfa-2b (Intron A).
- Sylatron is the first product approved specifically for adjuvant treatment of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection with complete lymphadenectomy.
- Black Box warning: Sylatron can cause life-threatening or fatal neuropsychiatric reactions. These include suicide, suicidal and homicidal ideation, depression, and an increased risk of relapse of recovering drug addicts.
- Other warnings include: cardiovascular (myocardial infarction, bundle branch block, ventricular tachycardia, and supraventricular arrhythmia), retinopathy, hepatic failure, and endocrinopathies (hypothyroidism, hyperthyroidism, and diabetes mellitus).

Eligibility Criteria

- Member must be eligible and have applicable benefits.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

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Background Information, continued:

Exclusions

- Hypersensitivity to peginterferon alfa-2b, interferon alfa-2b, other alfa interferons, or any component of the formulation.
- Autoimmune hepatitis and decompensated liver disease.

Procedure:

- 1.0 Request for *initiation* of therapy with Sylatron for **Melanoma** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying all of the following:
 - 1.1 Provider is medical oncologist; **AND**
 - 1.2 Diagnosis of melanoma with microscopic or gross nodal involvement; **AND**
 - 1.3 The melanoma must have been completely excised with adequate surgical margins and complete lymphadenectomy must have occurred within 84 days; **AND**
 - 1.4 If criteria are met, Sylatron can be given at six (6) mcg/kg/week subcutaneously for eight (8) doses followed by three (3) mcg/kg/week subcutaneously for up to five (5) years.

References:

1. Sylatron [Prescribing Information]. Shering Corporation. Kenilworth, NJ. March 2011.
2. Gold Standard, Inc. Sylatron. Clinical Pharmacology [database online]. Available at: <http://www.clinicalpharmacology.com>. Accessed: May 25, 2011.

Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.