Purpose:

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

Implementation Information:

1.0 Under the supervision of the Clinical Pharmacy Management (CPM) Director, the CPM staff is responsible for the development of guidelines and criteria for use by the Medical Department.

2.0 Staff utilizing this procedure is monitored via individual departmental audit tools.

3.0 Medical Department staff has access to the Medical Department Procedure Manual and receives notice from management when procedures are developed, updated and/or revised, or archived:

   3.1 On an annual basis or more often when indicated, the Medical Department Procedures are reviewed by medical staff for the purpose of developing, revising, or archiving.

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.
Medical Department Procedure Manual

Section: Chapter 7A Prescription Medication Prior Authorization  Number: 07.091

Title: peginterferon alfa-2b (Sylatron)  Page 2 of 3

Background Information, continued:

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.

Exclusions

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

Additional Information

- AvMed’s Clinical Pharmacists are licensed by the State of Florida.
- AvMed’s Medical Directors are Board Certified physicians licensed by the State of Florida.
Medical Department Procedure Manual

Section: Chapter 7A Prescription Medication Prior Authorization  Number: 07.091

Title: peginterferon alfa-2b (Sylatron)  Page 3 of 3

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;

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:
