PEG-INTERFERON ALFA-2B

Generic	Brand	HICL	GCN	Exception/Other
PEG-INTERFERON ALFA-2B	SYLATRON, SYLATRON 4-PACK		29809, 29811, 29812	

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Is the patient currently taking requested medication?

   If yes, continue to #2.
   If no, continue to #3.

2. Has the patient received 5 years of therapy with Sylatron?

   If yes, do not approve.
   DENIAL TEXT: Duration of therapy is limited to 5 years per FDA approved indication.
   If no, **approve for 12 months with a quantity limit of one 296mcg 4-pack or four 296mcg single dose kits per month.**
   APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

3. Does the patient have a diagnosis of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection?

   If yes, **approve. Enter two authorizations as follows:**
   - **2 months with a quantity limit of one 4-pack or four single dose kits per month, AND**
   - **10 months with a quantity limit of one 296mcg 4-pack or four 296mcg single dose kits per month with a start date 1 week prior to the end date of the authorization for 2 months.**
     APPROVAL TEXT: Please note that this drug has an important FDA safety warning. For more information, please ask your doctor or pharmacist.

   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection.

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RATIONALE

Ensure appropriate utilization of Sylatron based on FDA approved indication and NCCN guidelines. Peg-interferon in combination with wide excision is recommended for the treatment of Melanoma. Sylatron's dosing is weight based as follows: 6mcg/kg/week for 8 doses followed by 3mcg/kg/week subcutaneously for up to 5 years. This guideline approves the appropriate quantities for a patient weighing up to 98kg. Patients weighing over 98kg should be reviewed by clinical to determine the appropriate dose.

FDA APPROVED INDICATION

Sylatron is indicated for the adjuvant treatment of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy.

REFERENCES

- Eggermont AMM, Sucio S, Santinami M et al. Adjuvant therapy with pegylated interferon alfa-2b versus observation alone in resected stage III melanoma: final results of EORTC 18991, a randomised phase III trial. Lancet 200; 372:117-126.
- National Comprehensive Cancer Network, Inc. The NCCN Clinical Practice Guidelines in Oncology. Melanoma. (Version 4.2011).
- Schering Corporation. Sylatron package insert. Kenilworth, NJ. March 2011.
- Thomson Healthcare. Monograph Name. DRUGDEX® System [database online]. Greenwood Village, CO. Available at: https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction. [Accessed: June 22, 2011].

Part D Effective: N/A | Created: 05/11
Commercial Effective: 01/01/14 | Client Approval: 11/13 | P&T Approval: 11/13