RATIONAL FOR INCLUSION IN PA PROGRAM

Background
Sylatron (peginterferon alfa-2b) is an alfa interferon, a cytokine whose mechanism of action in patients with melanoma is unknown. Sylatron is used to prevent malignant melanoma from coming back after it has been removed by surgery. Sylatron should be started within 84 days of surgery on the melanoma (1-3).

Regulatory Status
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 (1).

Sylatron has a boxed warning regarding depression and other neuropsychiatric disorders. This warning addresses the risks of serious depression, with suicidal ideation and completed suicides, and other serious neuropsychiatric disorders. It is important to discontinue Sylatron in patients with persistently severe or worsening signs or symptoms of depression, psychosis, or encephalopathy. These disorders may not resolve after stopping Sylatron (1).

Sylatron is contraindicated in patients with a history of anaphylaxis reaction to peginterferon alfa-2b or interferon alfa-2b, autoimmune hepatitis, or hepatic decompensation (Child-Pugh score >6 [class B and C]) (1).

Summary
Sylatron is used to prevent malignant melanoma from coming back after it has been removed by surgery. Sylatron should be started within 84 days of surgery on the melanoma. Sylatron has a boxed warning regarding depression and other neuropsychiatric disorders (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Sylatron while maintaining optimal therapeutic outcomes.

References