Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

SYLATRON™ (peginterferon alfa-2b)

GPI CODING:

217000752064**

DESCRIPTION:

SYLATRON (peginterferon alfa-2b) is a covalent conjugate of recombinant alfa-2b interferon with monomethoxy polyethylene glycol. By binding to cell surface receptors, interferons have antiviral, antiproliferative and immunomodulating activity. The exact mechanism by which it exerts its effects in patients with melanoma is unknown. Peginterferon alfa-2b is Food and Drug Administration (FDA) approved for the adjuvant treatment of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy.

APPROVAL DURATION:

Initial approvals and renewals: 12 months.

CRITERIA FOR SYLATRON:

I. Patient is ≥18 years of age **AND**
II. Patient is being treated adjuvantly for melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy **OR**
III. Off label uses for oncology drugs if considered medically acceptable in one or more of the following compendia (i.e., Micromedex DrugDex, AHFS, Clinical Pharmacology, and NCCN.) *A use is identified by a compendium as medically accepted if the:*
    a. *Indication is a Category 1 or 2A in NCCN,*
    b. *Indication is a Class I, Class IIa or Class IIb in DrugDex,*
    c. *Narrative text in AHFS or Clinical Pharmacology is supportive; or*
    d. *The use is supported by clinical research in 2 or more peer-reviewed medical journals*

AND

IV. Patient does not have the following contraindications:
    a. Autoimmune hepatitis
    b. Hepatic decompensation (Child-Pugh score >6 [class B and C])

Authorization for continued use shall be reviewed at least every 12 months to confirm that the patient has experienced an objective response to therapy.