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HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

LIPODOX™ (doxorubicin hydrochloride liposomal injection)

Effective Date: 7/24/12

Date Developed: 7/3/12 by Albert Reeves MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19, 2/18/20, 2/2/21, 8/3/21, 2/1/22, 1/31/23, 2/13/24, 2/18/25

LIPODOX™(doxorubicin) is an anti-neoplastic anthracycline agent. Doxorubicin inhibits DNA and RNA synthesis. It is a pegylated formulation which protects the liposomes, and thereby increases blood circulation time.

Pre-Authorization Criteria:

AIDS-related Kaposi sarcoma: Treatment of AIDS-related Kaposi sarcoma (after failure of or intolerance to prior systemic therapy).

Multiple myeloma: Treatment of multiple myeloma (in combination with bortezomib) in patients who have not previously received bortezomib and have received at least 1 prior therapy.

Ovarian cancer, advanced: Treatment of progressive or recurrent ovarian cancer (after platinum-based chemotherapy).

Off-Label Use:

Breast cancer, metastatic; Castleman disease, multicentric (human herpesvirus-8-associated); Cutaneous T-cell lymphomas (mycosis fungoides and Sézary syndrome), recurrent or refractory; Diffuse large B-cell lymphoma; Hodgkin lymphoma (salvage treatment); Soft tissue sarcomas, advanced or metastatic; Uterine leiomyosarcoma, advanced or recurrent

NOTE: VCHCP requires that LOPODOX be prescribed by an O**ncologist.**

Dosage Forms:

2 mg/mL (25 mL) for IV infusion only

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Dosing: Adult

Details concerning dosing in combination regimens should also be consulted.

Liposomal formulations of doxorubicin should NOT be substituted for conventional doxorubicin hydrochloride on a mg-per-mg basis.

AIDS-related Kaposi's sarcoma: I.V.: 20 mg/m^2 every 3 weeks

Multiple myeloma: I.V.: 30 mg/m^2 on day 4 every 3 weeks (in combination with bortezomib) ~~**or**~~

Ovarian cancer: I.V.: 50 mg/m^2 every 4 weeks (minimum of 4 cycles is recommended)

Breast cancer, metastatic (unlabeled use): I.V.: 50 mg/m^2 every 4 weeks (Keller, 2004)

Uterine sarcoma (unlabeled use): I.V.: 50 mg/m^2 every 4 weeks (Sutton, 2005)

NOTE: **BMI ≥30 kg/m^2***:* Utilize patient's actual body weight for calculation of BSA- or weight-based dosing

NOTE: Administration:

Administer IVPB over 60 minutes; manufacturer recommends administering at initial rate of 1 mg/minute to minimize risk of infusion reactions until the absence of a reaction has been established, then increase the infusion rate for completion over 1 hour. Do **NOT** administer undiluted, as a bolus injection, or I.M. or SubQ.

If contact with skin/mucosa occurs, wash immediately with soap and water. Monitor for infusion reaction.

Adverse Reactions:

Bone marrow suppression, hepatic impairment, myocardial toxicity, nausea/vomiting, stomatitis, infusion related reactions

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