

Prior Authorization DRUG Guidelines

LIPODOX™ (doxorubicin hydrochloride liposome 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

LIPODOX™ is an anti-neoplastic agent, anthracycline

Pre-Authorization Criteria:

VCHCP will authorize LIPODOX for FDA indicated treatment of ovarian cancer (progressive or recurrent), multiple myeloma (after failure of at least 1 prior therapy), and AIDS-related Kaposi's sarcoma (after failure of or intolerance to prior systemic therapy)

Use - Unlabeled

Treatment of metastatic breast cancer, Hodgkin's lymphoma, cutaneous T-cell lymphomas (mycosis fungoides and Sézary syndrome), advanced soft tissue sarcomas; advanced or metastatic uterine sarcoma

VCHCP requires that LIPODOX be prescribed by an **Oncologist**.

Dosage Forms: U.S.

Excipient information presented when available (limited, particularly for generics); consult specific product labeling. Injection, solution, as hydrochloride: Doxil®: 2 mg/mL (10 mL, 25 mL) [contains soy, sucrose]

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.

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/m² every 3 weeks

Multiple myeloma: I.V.: 30 mg/m² on day 4 every 3 weeks (in combination with bortezomib) or

Unlabeled dosing: I.V.: 40 mg/m² every 4 weeks (in combination with vincristine and dexamethasone) (Rifkin, 2006)

Ovarian cancer: I.V.: 50 mg/m² every 4 weeks (minimum of 4 cycles is recommended)

Breast cancer (unlabeled use): I.V.: 50 mg/m² every 4 weeks (Keller, 2004)

Uterine sarcoma (unlabeled use): I.V.: 50 mg/m² every 4 weeks (Sutton, 2005)

Warnings/Precautions

Boxed warnings:

- Bone marrow suppression: See “Concerns related to adverse effects” below.
- Hepatic impairment: See “Disease-related concerns” below.
- Infusion reactions: See “Concerns related to adverse effects” below.
- Liposomal vs. conventional doxorubicin dosing: “Dosage form specific issues” below.
- Myocardial toxicity: See “Concerns related to adverse effects” below.

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1/24/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual review
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