

Market Applicability/Effective Date														
Market	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

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# Doxorubicin Hydrochloride Liposome Injection

CG-DRUG-49

Override	Approval Duration
Prior Authorization	1 year

Medications	Quantity Limit
Doxil	N/A
Doxorubicin hydrochloride (HCL) liposome	N/A
Lipodox	N/A

## APPROVAL CRITERIA

Requests for U.S. Food and Drug Administration-approved doxorubicin hydrochloride liposome injection **may be approved** for the treatment of **any** of the following indications:

- I. Breast cancer when used as a single agent for recurrent or metastatic disease; **OR**
- II. Kaposi's sarcoma, AIDS-related; **OR**
- III. Hodgkin's Lymphoma (for example, classical Hodgkin lymphoma or nodular lymphocytic predominant Hodgkin lymphoma) when used as second-line or subsequent therapy for refractory or relapsed disease; **OR**
- IV. Non-Hodgkin lymphoma; **OR**
- V. Multiple myeloma when agent used as second-line or later line of therapy; **OR**
- VI. Non-melanoma, dermatofibrosarcoma protuberans metastatic disease; **OR**
- VII. Ovarian cancer (including epithelial ovarian cancer, fallopian tube cancer, and primary peritoneal cancer) that is persistent or recurrent disease when **one** of the following is met:
  - a. Agent used as a single agent; **OR**
  - b. Agent used in combination with carboplatin or cisplatin; **OR**
  - c. Agent used in combination with bevacizumab, if bevacizumab was not previously used for treatment of ovarian cancer;

**OR**

- VIII. Sarcomas, soft tissue when **one** of the following is met:
  - a. Angiosarcoma when used as a single agent; **OR**
  - b. Desmoid tumors; **OR**
  - c. Retroperitoneal/Intra-abdominal sarcomas when used as a single agent; **OR**
  - d. Rhabdomyosarcoma when used as a single agent; **OR**

PAGE 1 of 5 07/26/2016

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- e. Soft tissue sarcoma of the extremity, superficial trunk, head or neck when used as a single agent;

**OR**

- IX. Uterine neoplasm when **one** of the following is met:
  - a. Endometrial carcinoma when used as a single agent; **OR**
  - b. Uterine sarcoma when used as a single agent for advanced or metastatic disease.

Doxorubicin hydrochloride liposome injection **may not be approved** when criteria above are not met and for all other indications including, but not limited to the treatment of endometrioid adenocarcinoma for isolated metastases.

State Specific Mandates		
N/A	N/A	N/A

**Key References:**

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