

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

Doxorubicin Hydrochloride Liposome Injection

Override	Approval Duration
Prior Authorization	1 year

Medications
Doxil
Doxorubicin hydrochloride (HCL) liposome
Lipodox

APPROVAL CRITERIA

Requests for Doxorubicin Liposome (Doxil, Lipodox) may be approved if the following criteria are met:

- I. Individual has a diagnosis of *one* of the following:
 - A. Breast cancer when used as monotherapy for recurrent or metastatic disease (NCCN 2A); **OR**
 - B. Kaposi's sarcoma, AIDS-related; **OR**
 - C. Hodgkin's Lymphoma (e.g. classical Hodgkin lymphoma or nodular lymphocytic predominant Hodgkin lymphoma) when used as second-line or subsequent therapy for refractory or relapsed disease (NCCN 2A); **OR**
 - D. Non-Hodgkin lymphoma (NCCN 2A); **OR**
 - E. Multiple myeloma when agent used as second-line or later line of therapy; **OR**
 - F. Non-melanoma, dermatofibrosarcoma protuberans metastatic disease (NCCN 2A); **OR**
 - G. 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:
 1. Agent used as monotherapy; **OR**
 2. Agent used in combination with carboplatin or cisplatin (NCCN 2A); **OR**
 3. Agent used in combination with bevacizumab, if bevacizumab was not previously used for treatment of ovarian cancer (NCCN 2A);
- OR**
- H. Sarcomas, soft tissue when *one* of the following is met (NCCN 2A):
 1. Angiosarcoma when used as monotherapy; **OR**
 2. Desmoid tumors; **OR**
 3. Retroperitoneal/Intra-abdominal sarcomas when used as monotherapy; **OR**
 4. Rhabdomyosarcoma when used as monotherapy; **OR**
 5. Soft tissue sarcoma of the extremity, superficial trunk, head or neck when used as monotherapy;

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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OR

- I. Uterine neoplasm when *one* of the following is met (NCCN 2A):
 1. Endometrial carcinoma when used as monotherapy; **OR**
 2. Uterine sarcoma when used as monotherapy for advanced or metastatic disease.

Requests for Doxorubicin Liposome (Doxil, Lipodox) may not be approved for the following:

- I. All other indications not included above; **OR**
- II. For the treatment of endometrioid adenocarcinoma for isolated metastases.

State Specific Mandates		
State Name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Aghajanian C, Blank SV, Goff BA, et al. OCEANS: a randomized, double-blind, placebo-controlled phase III trial of chemotherapy with or without bevacizumab in patients with platinum-sensitive recurrent epithelial ovarian, primary peritoneal, or fallopian tube cancer. *J Clin Oncol.* 2012; 30:2039-2045.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: March 28, 2019.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on March 28, 2019.
 - a. AIDS-Related Kaposi Sarcoma (V.2 2019). Revised November 29, 2018.
 - b. B-Cell Lymphomas (V.2.2019). Revised March 6, 2019.
 - c. Breast cancer (V.1.2019). Revised March 14, 2019.
 - d. Dermatofibrosarcoma protuberans (V.1.2019). Revised August 31, 2018.
 - e. Hodgkin Lymphoma (V.3.2018). Revised April 16, 2018.
 - f. Multiple myeloma (V.2.2019). Revised November 16, 2018.
 - g. Ovarian cancer (V.1.2019). Revised March 8, 2019.
 - h. Soft tissue sarcoma (V.2.2019). Revised February 4, 2019.
 - i. T-Cell Lymphomas (V.2.2019). Revised December 17, 2018.
 - j. Uterine neoplasms (V.3.2019). Revised February 11, 2019.
7. Pujade-Lauraine E, Hilpert F, Weber B, et al. Bevacizumab combined with chemotherapy for platinum-resistant recurrent ovarian cancer: The AURELLIA open-label randomized phase III trial. *J Clin Oncol.* 2014; 32:1302-1308.

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