

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. 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 (NCCN 1, 2A); **OR**
 3. Agent used in combination with bevacizumab (or bevacizumab biosimilar), if bevacizumab was not previously used for treatment of ovarian cancer (NCCN 2A); **OR**
 4. Agent used in combination with carboplatin *and* bevacizumab (or bevacizumab biosimilar), if bevacizumab was not previously used for treatment of ovarian cancer (NCCN 1, 2A);
- OR**
- G. 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**

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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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4. Rhabdomyosarcoma when used as monotherapy; **OR**
5. Soft tissue sarcoma of the extremity, superficial trunk, head or neck when used as monotherapy;

OR

- H. 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.

Doxorubicin Liposome (Doxil, Lipodox) may not be approved when the above criteria are not met and for all other indications.

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.: 2020. 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: April 15, 2020.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on April 15, 2020.
 - a. AIDS-Related Kaposi Sarcoma V1.2020. Revised February 12, 2020.
 - b. B-Cell Lymphomas V1.2020. Revised January 22, 2020.
 - c. Breast cancer V3.2020. Revised March 6, 2020.
 - d. Hodgkin Lymphoma V1.2020. Revised January 30, 2020.
 - e. Multiple myeloma V3.2020. Revised March 10, 2020.
 - f. Ovarian cancer V1.2020. Revised March 11, 2020.
 - g. Primary Cutaneous Lymphomas V2.2020. Revised April 10, 2020.
 - h. Soft tissue sarcoma V6.2019. Revised February 10, 2020.
 - i. T-Cell Lymphomas V1.2020. Revised January 6, 2020.
 - j. Uterine neoplasms V1.2020. Revised March 6, 2020.
7. Pfisterer J, Shannon CM, Baumann K, et al; AGO-OVAR 2.21/ENGOT-ov 18 Investigators. Bevacizumab and platinum-based combinations for recurrent ovarian cancer: a randomised, open-label, phase 3 trial. *Lancet Oncol.* 2020 Apr 16. pii: S1470-2045(20)30142-X. doi: 10.1016/S1470-2045(20)30142-X. [Epub ahead of print]
8. 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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