

Doxorubicin Hydrochloride Liposome Injection

Override	Approval Duration
Prior Authorization	1 year

Medications
Doxil
Doxorubicin hydrochloride (HCL) liposome

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) 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. Dermatofibrosarcoma protuberans (DFSP) with fibrosarcomatous transformation used as monotherapy; **OR**
 3. Dedifferentiated chordoma used as monotherapy; **OR**
 4. Desmoid tumors; **OR**
 5. Retroperitoneal/Intra-abdominal sarcomas when used as monotherapy; **OR**
 6. Rhabdomyosarcoma when used as monotherapy; **OR**
 7. Soft tissue sarcoma of the extremity, superficial trunk, head or neck when used as monotherapy; **OR**

8. Solitary fibrous tumor 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.

Note:

There is a black box warning with doxorubicin liposome for cardiomyopathy (including congestive heart failure) and infusion-related reactions consisting of, but not limited to, flushing, shortness of breath, facial swelling, headache, chills, back pain, tightness in the chest or throat, and/or hypotension.

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.; 2022. 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 29, 2022.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2021 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on March 29, 2022.
 - a. B-Cell Lymphomas V1.2022. Revised March 21, 2022.
 - b. Breast cancer V2.2022. Revised December 20, 2021.
 - c. Hodgkin Lymphoma V2.2022. Revised February 23, 2022.
 - d. Kaposi Sarcoma V1.2022. Revised February 3, 2022.
 - e. Multiple myeloma V5.2022. Revised March 9, 2022.
 - f. Ovarian cancer V1.2023. Revised December 22, 2022.
 - g. Primary Cutaneous Lymphomas V1.2022. Revised January 26, 2022.
 - h. Soft tissue sarcoma V1.2022. Revised March 29, 2022.
 - i. T-Cell Lymphomas V2.2022. Revised March 7, 2022.
 - j. Uterine neoplasms V1.2022. Revised November 4, 2021.
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.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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