

POLICY NUMBER UM_ONC_1235	SUBJECT Doxil/Lipodox™ (liposomal doxorubicin)	DEPT/PROGRAM UM Dept	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 12/12/12, 12/11/13, 03/27/15, 05/24/16, 04/08/20	APPROVAL DATE April 8, 2020	EFFECTIVE DATE April 24, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 12/12/12, 12/11/13, 03/27/15, 05/24/16, 04/08/20
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee	
URAC STANDARDS HUM 1		NCQA UM 2	ADDITIONAL AREAS OF IMPACT
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS	APPLICABLE LINES OF BUSINESS All	

I. PURPOSE

To define and describe the accepted indications for Doxil/Lipodox (liposomal doxorubicin) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

1. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

- When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**
- When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**
- For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies: **Error! Hyperlink reference not valid.AND**
- Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
- When available, generic alternatives are preferred over brand-name drugs.

2. NOTE: The preferred agent, per NCH Policies, is standard Doxorubicin (Adriamycin) when used for Hodgkin lymphoma and breast cancer.

3. Aids related Kaposi's Sarcoma (KS)

- For the treatment of HIV-related Kaposi's sarcoma in members with disease that has progressed on prior combination chemotherapy or in members who are intolerant to other therapy.



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4. Multiple Myeloma

- a. **NOTE: Please refer to NCH Pathway for L1 preferred regimens/agents for initial and subsequent therapy for Multiple Myeloma.**

5. Ovarian cancer

- a. In combination with Carboplatin for platinum sensitive relapsed/recurrent ovarian cancer
- b. As a single agent for platinum-resistant relapsed/recurrent ovarian cancer.

III. EXCLUSION CRITERIA

1. Disease progression while taking Doxil/Lipodox (liposomal doxorubicin).
2. Members with cardiomyopathy and those receiving concurrent radiation over the heart.
3. Dosing exceeds single dose limit of Doxil/Lipodox (liposomal doxorubicin) 50 mg/m².
4. Dosing exceeds the total cumulative doses of 550 mg/m².
5. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

1. Review – UM Department
2. Final Approval – UM Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Doxil prescribing information. Janssen Products, LP Horsham, PA 2019.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists. Bethesda, MD. 2020.