

Drug Policy:

Vyxeos™ (daunorubicin and cytarabine liposomal)

POLICY NUMBER UM ONC_1326	SUBJECT Vyxeos™ (daunorubicin and cytarabine liposomal)	DEPT/PROGRAM UM Dept	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 09/13/17, 09/21/18, 08/14/19, 12/11/19, 08/12/20	APPROVAL DATE August 12, 2020	EFFECTIVE DATE August 28, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 09/13/17, 09/21/18, 08/14/19, 12/11/19, 08/12/20
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee	
URAC STANDARDS HUM 1	NCQA STANDARDS 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 Vyxeos (daunorubicin and cytarabine liposomal) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH 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

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. 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](#)

2. 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](#)
3. 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 [AND](#)
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision [AND](#)
5. When available, generic alternatives are preferred over brand-name drugs.

B. Acute Myeloid Leukemia (AML)

1. NOTE: Per NCH Policy and NCH Pathway, Vyxeos (daunorubicin and cytarabine liposomal) is a non-preferred drug for the treatment of AML for any line of therapy. Generic daunorubicin and cytarabine are the preferred agents in this setting.

III. EXCLUSION CRITERIA

- A. Dosing exceeds single dose limit of Vyxeos: 44 mg/m² daunorubicin liposomal and 100 mg/m² cytarabine liposomal (for induction) or 29 mg/m² daunorubicin liposomal and 65 mg/m² cytarabine liposomal (for consolidation).
- B. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

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

V. APPROVAL AUTHORITY

- A. Review – Utilization Management Department
- B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

- A. None

VII. REFERENCES

- A. Vyxeos prescribing information. Jazz Pharmaceuticals, Inc. Palo Alto, CA 2019.
- B. Clinical Pharmacology Elsevier Gold Standard. 2020.
- C. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
- D. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
- E. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.