Daunorubicin and Cytarabine, Liposome (Vyxeos®)

NDC CODE(S) 68727-0745-XX VYXEOS 100MG-44MG Solution Reconstituted (JAZZ PHARMACEUTICALS)

DESCRIPTION

Daunorubicin and cytarabine, liposome is a combination of daunorubicin and cytarabine encapsulated in liposomes. Daunorubicin, an anthracycline topoisomerase inhibitor, inhibits DNA polymerase activity and produces DNA-damaging free radicals. Cytarabine is a nucleoside metabolic inhibitor which works as a cell cycle phase-specific antineoplastic agent during the S-phase of cell division. Liposomes enter the bone marrow where they appear to be taken up by leukemic cells more readily than normal bone marrow cells. There, the liposomes undergo degradation, releasing the daunorubicin and cytarabine within the bone marrow cellular environment where they work synergistically to kill leukemic cells.

POLICY

- Daunorubicin and cytarabine liposome for injection for the treatment of Acute Myeloid Leukemia (AML) is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- Daunorubicin and cytarabine liposome for injection for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL CRITERIA

- Patient is at least 18 years of age (unless otherwise specified); **AND**
- Baseline left ventricular ejection fraction (LVEF) is within normal limits and will be reassessed prior to consolidation and as clinically required; **AND**
- Cumulative lifetime anthracycline (e.g., daunorubicin, etc.) dose does not exceed 550 mg/m^2 (or 400 mg/m^2 in patients who received radiation to the mediastinum); **AND**
- Will not be used in combination with other chemotherapy; **AND**

Acute Myeloid Leukemia (AML)

- Patient has one of the following sub-types of disease:
  - Therapy-related acute myeloid leukemia (t-AML)
  - AML with myelodysplasia-related changes (AML-MRC)
  - Antecedent myelodysplastic syndrome/chronic myelomonocytic leukemia (antecedent MDS/CMML); **AND**
- Used for one of the following:
  - Patient is at least 1 year of age with newly diagnosed disease *(Note: For antecedent MDS/CMML, use is only allowed in patients age ≥ 60 years of age that are candidates for intensive remission induction therapy)*; **OR**
  - Used ~~for~~ as re-induction therapy after standard-dose cytarabine induction therapy; **AND**
    - Patients ≥ 60 years of age with residual disease; **OR**
    - Patients < 60 years of age with significant residual disease in the absence of a hypocellular marrow and core binding factor (CBF) abnormalities; **OR**
  - Used as post-remission therapy; **AND**
    - Patients ≥ 60 years of age with complete response to previous intensive therapy; **OR**

- Patients < 60 years of age with treatment-related disease other than core binding factor (CBF) and/or unfavorable cytogenetics and/or molecular abnormalities

RENEWAL CRITERIA

Authorizations may not be renewed.

DOSAGE/ADMINISTRATION

INDICATION	DOSE
t-AML, antecedent MDS/CMML & AML-MRC	First induction • daunorubicin 44 mg/m^2 and cytarabine 100 mg/m^2 liposome intravenously days 1, 3 and 5 Second induction • daunorubicin 44 mg/m^2 and cytarabine 100 mg/m^2 liposome intravenously days 1 and 3 ○ Only for patients who fail to respond to the first induction cycle ○ May be administered 2 to 5 weeks after the first induction cycle if there was no unacceptable toxicity Consolidation • daunorubicin 29 mg/m2 and cytarabine 65 mg/m^2 liposome intravenously days 1 and 3 ○ Administer the first consolidation cycle 5 to 8 weeks after the start of the last induction cycle ○ Administer the second consolidation cycle 5 to 8 weeks after the start of the first consolidation cycle if there was not unacceptable toxicity or disease progression

LENGTH OF AUTHORIZATION

Coverage will be provided for a maximum of 2 cycles of induction (5 doses total) and 2 cycles of consolidation (4 doses total) within 6 months. Coverage may not be renewed.

DOSING LIMITS

Max Units (per dose and over time) [HCPCS Unit]:

- Induction: 132 billable units per dose (3 vials per dose; 5 doses total)
- Consolidation: 88 billable units per dose (2 vials per dose; 4 doses total)

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

1. Vyxeos [package insert]. Palo Alto, CA; Jazz Pharmaceuticals, Inc., March 2021. Accessed March 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for cytarabine/daunorubicin liposome. National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2021.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Acute Myeloid Leukemia. Version 3.2021. National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2021.
4. Lin TL, Ryan RJ, Fadert S, et al. Outcomes in older patients with high-risk/secondary AML who achieved remission with CPX-351 versus 7+3 but did not undergo transplant: Phase 3 exploratory analysis. J Clin Onco; DOI: 10.1200/JCO.2020.38.15_suppl.7537 Journal of Clinical Oncology38, no. 15_suppl(May 20, 2020)7537-7537.
5. Lexi-Comp Online. (2021, February). AHFS DI. *Daunorubicin and Cytarabine*. Retrieved April 19, 2021 from Lexi-Comp Online with AHFS.
6. MICROMEDEX Healthcare Series. Drugdex Drug Evaluations. (2021, March). *Daunorubicin and Cytarabine, Liposome*. Retrieved April 19, 2021 from MICROMEDEX Healthcare Series.

EFFECTIVE DATE 8/31/2021

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