Daunorubicin and Cytarabine, Liposome (Vyxeos®)

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 or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has newly-diagnosed therapy-related acute myeloid leukemia (t-AML)
  AND
  - The patient is 1 year of age or older
  AND
  - The provider has verified the patient's prior cumulative anthracycline exposure and deemed therapy with Vyxeos necessary and appropriate
  AND
  - The patient has a baseline left ventricular ejection fraction (LVEF) within normal limits and the patient's LVEF will be reassessed as clinically required

OR

- The patient has a diagnosis of acute myeloid leukemia with myelodysplasia-related changes (AML-MRC)
  AND
  - The patient is 1 year of age or older
  AND
  - The provider has verified the patient's prior cumulative anthracycline exposure and deemed therapy with Vyxeos necessary and appropriate
  AND
  - The patient has a baseline left ventricular ejection fraction (LVEF) within normal limits and the patient's LVEF will be reassessed as clinically required

*The NCCN Drugs & Biologics Compendium recognizes additional uses for Daunorubicin and Cytarabine, Liposome beyond the FDA-approved labeling (Refer to the NCCN Drugs & Biologics Compendium or NCCN Clinical Practice Guidelines for detailed recommendations)

LENGTH OF AUTHORIZATION

Approval may be provided for six (6) months. Administration may also be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

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.

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).

REFERENCES

1. Vyxeos [package insert]. Palo Alto, CA; Jazz Pharmaceuticals, Inc., 2022. Accessed August 2024.
2. Vyxeos. In: Clinical Pharmacology. Tampa (FL): Elsevier. Revised January 2024. Accessed August 2024.
3. Lexi-Comp Online. (2024, March). AHFS DI. Daunorubicin and Cytarabine. Retrieved August 2024 from Lexi-Comp Online with AHFS.
4. MICROMEDEX Healthcare Series. Drugdex Evaluations. (2024, April). Daunorubicin and Cytarabine. Retrieved May 2024 from MICROMEDEX Healthcare Series.
5. The NCCN Drugs & Biologics Compendium 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed August 7, 2024.

EFFECTIVE DATE 12/31/2024

ID_BT