PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Vyxeos Prior Authorization Policy
- Vyxeos® (daunorubicin and cytarabine liposome intravenous infusion – Jazz)

REVIEW DATE: 12/18/2024

OVERVIEW
Vyxeos is a liposomal combination of daunorubicin, an anthracycline topoisomerase inhibitor, and cytarabine, a nucleoside metabolic inhibitor. It is indicated for the treatment of newly-diagnosed therapy-related **acute myeloid leukemia** (AML) or **AML with myelodysplasia-related changes** in patients ≥ 1 year of age.[1]

Guidelines
The National Comprehensive Cancer Network guidelines for **acute myeloid leukemia** (version 3.2024 – May 17, 2024) recommend Vyxeos for induction and post-remission therapy for patients with therapy-related AML, antecedent myelodysplastic syndrome/chronic myelomonocytic leukemia, and AML with myelodysplasia-related changes.[2,3]

POLICY STATEMENT
Prior Authorization is recommended for prescription benefit coverage of Vyxeos. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Vyxeos as well as the monitoring required for adverse events and long-term efficacy, approval requires Vyxeos to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Vyxeos is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Acute Myeloid Leukemia.** Approve for 6 months if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 1 year of age; AND
   - **B)** Patient meets ONE of the following (i or ii):
     - **i.** Patient has therapy-related acute myeloid leukemia; OR
     - **ii.** Patient has secondary acute myeloid leukemia; AND
       Note: Examples include antecedent myelodysplastic syndrome/chronic myelomonocytic leukemia and acute myeloid leukemia with myelodysplasia-related changes.
   - **C)** The medication is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Vyxeos is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Vyxeos liposome intravenous infusion [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals; September 2022.
2. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 16, 2024. Search term: Vyxeos.
3. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 3.2024 – May 17, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 16, 2024.