Medical Policy:

Vyxeos (daunorubicin and cytarabine)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.52	January 2, 2025	December 3, 2018

Definitions

Vyxeos (daunorubicin and cytarabine) is a liposomal combination of cytarabine, a nucleoside metabolic inhibitor that exhibits antineoplastic effects during the S-phase of cell division, and daunorubicin, an anthracycline topoisomerase inhibitor, that exhibits antimitotic and cytotoxic activity. It is indicated for induction and consolidation in acute myeloid leukemia.

Length of Authorization

Approval will be granted for 6 months and may not be renewed

Dosing Limits [Medical Benefit]

Max units (per dose and over time):

- Induction/Re-Induction (Second Induction): 132 billable units per dose (3 vials per dose; 6 doses total)
- Consolidation: 88 billable units per dose (2 vials per dose; 4 doses total)

Guideline

I. INITIAL CRITERIA

Vyxeos (daunorubicin and cytarabine) may be considered medically necessary for the treatment of **newly diagnosed therapy-related Acute Myeloid Leukemia (t-AML), or AML with myelodysplasia-related changes (AML-MRC) w**hen all of the following criteria are met:

1. **Acute Myeloid Leukemia.** Approve if the patient meets the following criteria (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.

Limitations/Exclusions

- Approval will be granted for 6 months and may not be renewed

Applicable Procedure Codes

Code	Description
J9153	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine (1 billable unit)

Applicable NDCs

Code	Description
68727-0745-XX	Vyxeos (44mg daunorubicin and 100mg cytarabine) liposome, single dose vial

ICD-10 Diagnoses

Code	Description
C92.00	Acute myeloblastic leukemia not having achieved remission
C92.01	Acute myeloblastic leukemia in remission
C92.50	Acute myelomonocytic leukemia not having achieved remission
C92.51	Acute myelomonocytic leukemia in remission
C92.60	Acute myeloid leukemia with 11q23-abnormality not having achieved remission
C92.61	Acute myeloid leukemia with 11q23-abnormality in remission
C92.A0	Acute myeloid leukemia with multilineage dysplasia not having achieved remission
C92.A1	Acute myeloid leukemia with multilineage dysplasia in remission
C93.00	Acute monoblastic/monocytic leukemia not having achieved remission
C93.01	Acute monoblastic/monocytic leukemia in remission

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/2/2025	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	1/2/2024	Annual Review: Updated Dosing Limits and ICD-10 codes
EmblemHealth & ConnectiCare	3/14/2023	Annual Review: Updated age from 18 years to greater than one year of age. Removed: Baseline left ventricular ejection fraction (LVEF) within normal limits (at least 50%); AND Cumulative lifetime anthracycline (e.g., daunorubicin, etc.) dose does not exceed 550 mg/m2 (or 400 mg/m2 in patients who received radiation to the mediastinum); AND Patient has newly diagnosed disease; AND Will not be used in combination with other chemotherapy. Added: The medication is prescribed by or in consultation with an oncologist.
EmblemHealth & ConnectiCare	1/18/2023	Transfer to New Template
EmblemHealth & ConnectiCare	12/30/2020	Annual review: no policy changes
EmblemHealth & ConnectiCare	11/4/2019	Annual review
EmblemHealth & ConnectiCare	12/3/2018	Added J9153 and removed J9999, C9024 from Applicable Procedure Codes.

References

1. Vyxeos [package insert]. Palo Alto, CA; Jazz Pharmaceuticals, Inc.,July, 2019. Accessed December, 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Acute Myeloid Leukemia. Version 1.2018. National Comprehensive Cancer Network, 2018. 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 April 2018.