



Vyxeos™ (daunorubicin and cytarabine)

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Medical Guideline Disclaimer

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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 antimetabolic and cytotoxic activity. It is indicated for induction and consolidation in acute myeloid leukemia.

Dosing

Max units (per dose and over time):

- Induction: 132 billable units on days 1, 3, and 5 of the first induction cycle and days 1 and 3 of the second induction cycle
- Consolidation: 88 billable on day 1 and 3 of the first and second consolidation cycle

Guideline

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) when all of the following criteria are met:

- Patient is at least 18 years old; **AND**
- Baseline left ventricular ejection fraction (LVEF) within normal limits; **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

Limitations/Exclusions

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

Revision History

12/3/2018	– Added J9153 and removed J9999, C9024 from Applicable Procedure Codes.
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Applicable Procedure Codes

J9153	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine (1 billable unit)
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Applicable NDCs

68727-0745-XX	Vyxeos (44mg daunorubicin and 100mg cytarabine) liposome, single dose vial
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Applicable Diagnosis Codes

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
C94.00	Acute erythroid leukemia not having achieved remission
C94.01	Acute erythroid leukemia in remission
C94.20	Acute megakaryoblastic leukemia not having achieved remission
C94.21	Acute megakaryoblastic leukemia in remission

References

1. Vyxeos [package insert]. Palo Alto, CA; Jazz Pharmaceuticals, Inc., August 2017. Accessed April 2018.
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.