Daunorubicin and cytarabine (Vyxeos®) liposome for injection	Place of Service Office Administration Infusion Center Administration Outpatient Facility Administration Home Infusion HCPCS: J9153, Daunorubicin per 1 mg AND Cytarabine per 2.27 mg

Condition(s) listed in policy (*see criteria for details*)

- Acute myeloid leukemia (AML) with myelodysplasia-related changes (AML-MRC)
- Antecedent myelodysplastic syndrome/chronic myelomonocytic leukemia (MDS/CMML)
- Therapy-related acute myeloid leukemia (t-AML)

AHFS therapeutic class: Antineoplastic agent
Mechanism of action: Daunorubicin is an anthracycline topoisomerase inhibitor. Cytarabine is a nucleoside metabolic inhibitor.

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Vyxeos® (daunorubicin and cytarabine liposome) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

AML with myelodysplasia-related changes (AML-MRC), OR Antecedent myelodysplastic syndrome/chronic myelomonocytic leukemia (MDS/CMML), OR Therapy-related acute myeloid leukemia (t-AML)

Covered doses

Induction:

- 1st induction: up to daunorubicin 44 mg/m^2 and cytarabine 100 mg/m^2 liposome IV on days 1, 3, and 5.
- 2nd and 3rd induction (If needed, two to five weeks after prior induction): same dose on days 1 and 3 of second or third induction.

Consolidation/Post-remission:

- Following 5 to 8 weeks post-induction, up to daunorubicin 29 mg/m^2 and cytarabine 65 mg/m^2 liposome IV on days 1 and 3 of each consolidation cycle for up to two cycles, administered at 5 to 8 weeks apart.

Coverage period

Up to three induction cycles and up to two consolidation cycles over six months

ICD-10:

C92.00, C92.01, C92.50, C92.51, C92.60, C92.61, C92.A0, C92.A1, C93.00, C93.01, C94.00, C94.01, C94.20, C94.21

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Vyxeos® (daunorubicin and cytarabine liposome) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

44 mg daunorubicin with 100 mg cytarabine liposomes (single-dose vials)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- National Comprehensive Cancer Network. Acute Myeloid Leukemia (Version 2.2023). Available at: www.nccn.org.
- Vyxeos (daunorubicin and cytarabine) [Prescribing Information]. Palo Alto, CA: Jazz Pharmaceuticals; 9/2022.

(7) Policy Update

Date of last review: 2Q2023

Date of next review: 2Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.