

Vyxeos® (daunorubicin and cytarabine – liposome) (Intravenous)

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I. Length of Authorization

- Coverage will be provided for a maximum of 2 cycles of induction (6 doses total) and 2 cycles of consolidation (4 doses total) within 6 months. Coverage may not be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Vyxeos single-dose vial: 26 vials total

B. Max Units (per dose and over time) [HCPCS Unit]:

- 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)

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 1 year of age (unless otherwise specified); **AND**
- Baseline left ventricular ejection fraction (LVEF) is within normal limits and will be reassessed prior to consolidation and as clinically required; **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**
- Will not be used in combination with other chemotherapy; **AND**

Acute Myeloid Leukemia (AML) † ‡ Φ ¹⁻³

- Patient has one of the following sub-types of disease:
 - Therapy-related acute myeloid leukemia (t-AML)
 - AML with myelodysplasia-related changes (AML-MRC)

- Antecedent myelodysplastic syndrome/chronic myelomonocytic leukemia (antecedent MDS/CMML) (*Note: For antecedent MDS/CMML, use is only allowed in patients age \geq 60 years of age that are candidates for intensive induction therapy*); **AND**
- Used for one of the following:
 - Used as induction therapy for newly diagnosed disease; **OR**
 - Used as re-induction therapy after standard-dose cytarabine induction therapy ‡; **AND**
 - Used in patients with significant residual disease in the absence of hypocellular marrow and core binding factor (CBF) abnormalities; **OR**
 - Used as consolidation therapy

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria ^{1,3}

Authorizations may not be renewed.

V. Dosage/Administration ^{1,3}

Indication	Dose
t-AML, antecedent MDS/CMML & AML-MRC	<u>First Induction</u>
	<ul style="list-style-type: none"> • daunorubicin 44 mg/m² and cytarabine 100 mg/m² liposome intravenously days 1, 3 and 5 for 1 cycle
	<u>Re-Induction (Second Induction)</u>
	<ul style="list-style-type: none"> • daunorubicin 44 mg/m² and cytarabine 100 mg/m² liposome intravenously days 1, 3 and 5 for 1 cycle <ul style="list-style-type: none"> ○ Only for patients who fail to respond to the first induction cycle ○ May be administered 2 to 5 weeks after the first induction cycle if there was no unacceptable toxicity
	<u>Consolidation</u>
	<ul style="list-style-type: none"> • daunorubicin 29 mg/m² and cytarabine 65 mg/m² liposome intravenously days 1 and 3 for 1 to 2 cycles <ul style="list-style-type: none"> ○ Administer the first consolidation cycle 5 to 8 weeks after the start of the last induction cycle ○ Administer the second consolidation cycle 5 to 8 weeks after the start of the first consolidation cycle if there was no unacceptable toxicity or disease progression

VI. Billing Code/Availability Information

HCP Code:

- J9153 – Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine; 1 billable unit = 1 mg daunorubicin and 2.27 mg cytarabine

NDC:

VYXEOS® (daunorubicin and cytarabine - liposome)
Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.
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- Vyxeos (44 mg daunorubicin and 100 mg cytarabine) liposome, single-dose vial: 68727-0745-xx

VII. References

1. Vyxeos [package insert]. Palo Alto, CA; Jazz Pharmaceuticals, Inc., September 2022. Accessed June 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for cytarabine/daunorubicin liposome. National Comprehensive Cancer Network, 2023. 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 June 2023.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Acute Myeloid Leukemia. Version 3.2023. National Comprehensive Cancer Network, 2023. 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 June 2023.
4. Lin TL, Ryan RJ, Fadert S, et al. Outcomes in older patients with high-risk/secondary AML who achieved remission with CPX-351 versus 7+3 but did not undergo transplant: Phase 3 exploratory analysis. J Clin Onco; DOI: 10.1200/JCO.2020.38.15_suppl.7537 Journal of Clinical Oncology 38, no. 15_suppl(May 20, 2020)7537-7537.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 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

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

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PreferredOne Community Health Plan ("PCHP") complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PCHP does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

PCHP:

Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.800.940.5049 (TTY: 763.847.4013).

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ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፡ በነጻ ሊያገዝዎት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (መስማት ለተሳናቸው: 763.847.4013) .

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PreferredOne Insurance Company
PO Box 59212
Minneapolis, MN 55459-0212
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Fax: 763.847.4010
customerservice@preferredone.com

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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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