

## 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 <sup>1</sup>

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/m<sup>2</sup> (or 400 mg/m<sup>2</sup> in patients who received radiation to the mediastinum); **AND**
- Will not be used in combination with other chemotherapy; **AND**

#### Acute Myeloid Leukemia (AML) † ‡ Φ <sup>1-3</sup>

- 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 <sup>1,3</sup>

Authorizations may not be renewed.

#### V. Dosage/Administration <sup>1,3</sup>

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

#### 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

## Nondiscrimination & Language Access Policy

Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity. We do not exclude people or treat them differently because of race, color, national origin, age, disability, sex, sexual orientation, or gender identity.

We will:

Provide 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)

Provide 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 us at the phone number shown on the inside cover of this contract, your id card, or aspirushealthplan.com.

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

Nondiscrimination Grievance Coordinator  
Aspirus Health Plan, Inc.  
PO Box 1062  
Minneapolis, MN 55440  
Phone: 1.866.631.5404 (TTY: 711)  
Fax: 763.847.4010  
Email: customerservice@aspirushealthplan.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Nondiscrimination Grievance Coordinator 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

**Albanian:** KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1.866.631.5404 (TTY: 711).

**Arabic:** تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلی رقم الهاتف 1.866.631.5404 (رقم هاتف الصم والبك : 711)

**French:** ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelezle 1.866.631.5404 (ATS : 711).

**German:** ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.866.631.5404 (TTY: 711).

**Hindi:** \_यान द\_ : य\_द आप िहंदी बोलते ह\_ तो आपके िलए मु\_त म\_ भाषा सहायता सेवाएं उपल\_ध ह\_। 1.866.631.5404 (TTY: 711) पर कॉल कर\_।

**Hmong:** LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.866.631.5404 (TTY: 711).

**Korean:** 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.866.631.5404 (TTY: 711)번으로 전화해 주십시오.

**Polish:** UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1.866.631.5404 (TTY: 711).

**Russian:** ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.866.631.5404 (телетайп: 711).

**Spanish:** ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.631.5404 (TTY: 711).

**Tagalog:** PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1.866.631.5404 (TTY: 711)

**Traditional Chinese:** 注意: 如果您使用繁體中文, 您可以免費獲得語言援助服務。請致電 1.866.631.5404 (TTY: 711)。

**Vietnamese:** CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.866.631.5404 (TTY: 711).

**Pennsylvania Dutch:** Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1.866.631.5404 (TTY: 711).

**Lao:** ໄປດຊາຍ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1.866.631.5404 (TTY: 711).