

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 (5 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) [Pharmacy Benefit]:

- Vyxeos single-dose vial: 23 vials total

B. Max Units (per dose and over time) [Medical Benefit]:

- Induction: 132 billable units per dose (3 vials per dose; 5 doses total)
- Consolidation: 88 billable units per dose (2 vials per dose; 4 doses total)

III. Initial Approval Criteria

Coverage is provided in the following conditions:

Therapy-related Acute Myeloid Leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) †

- 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**
- Will not be used in combination with other chemotherapy; **AND**
- Used for one of the following:
 - Patient has newly diagnosed disease; **OR**
 - Used for re-induction after standard-dose cytarabine induction ‡; **AND**
 - Patients ≥ 60 years with residual disease; **OR**

- Patients < 60 years with significant residual disease in the absence of a hypocellular marrow and core binding factor (CBF) abnormalities; **OR**
- Used post-remission †; **AND**
 - Patients ≥ 60 years with complete response to previous intensive therapy; **OR**
 - Patients < 60 years in the absence of core binding factor (CBF) abnormalities, treatment-related disease, poor-risk cytogenetics, or molecular abnormalities

† FDA Approved Indication(s); ‡ Compendia recommended indication(s)

IV. Renewal Criteria

Authorizations may not be renewed.

V. Dosage/Administration

Indication	Dose
t-AML & AML-MRC	<p><u>First Induction</u></p> <ul style="list-style-type: none"> • daunorubicin 44 mg/m² and cytarabine 100 mg/m² liposome intravenously days 1, 3 and 5 <p><u>Second induction</u></p> <ul style="list-style-type: none"> • daunorubicin 44 mg/m² and cytarabine 100 mg/m² liposome intravenously days 1 and 3 <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 <p><u>Consolidation</u></p> <ul style="list-style-type: none"> • daunorubicin 29 mg/m² and cytarabine 65 mg/m² liposome intravenously days 1 and 3 <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 not unacceptable toxicity of disease progression

VI. Billing Code/Availability Information

HCPCS code:

- J9153 – Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine: 1 billable unit = 1 mg/2.27 mg as daunorubicin/cytarabine, respectively (effective 1/1/19)
- J9999 – Not otherwise classified antineoplastic drugs

- C9024 – Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine; 1 billable unit = 1 mg/2.27 mg as daunorubicin/cytarabine, respectively (Effective 1/1/2018 for HOPPS) (inactive 1/1/19)

NDC:

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., August 2017. Accessed May 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for cytarabine/daunorubicin liposome. 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 May 2018.
3. 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 May 2018.

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
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

Vyxeos™ (daunorubicin and cytarabine) Prior Auth Criteria

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ICD-10	ICD-10 Description
C94.21	Acute megakaryoblastic 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) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-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): 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 Government Benefit Administrators, 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