



VYXEOS Reimbursement Guide

Overview

Jazz is committed to innovation in hematology/oncology with potential new therapeutic options and research and development efforts focused on expanding the science behind our medicines.

This Reimbursement Guide is focused on **VYXEOS**, which is indicated for the treatment of newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) in adults and pediatric patients 1 year and older.

NCCN

Liposomal daunorubicin and cytarabine (VYXEOS) is a recommended treatment option in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for induction in patients ≥60 years of age with therapy-related acute myeloid leukemia (t-AML) or antecedent MDS/CMM¹ or AML with myelodysplasia-related changes (AML-MRC) (Category 1)^{1,a}

^aNCCN makes no representations or warranties of any kind regarding their content, use or application and disclaims any responsibility for their application or use in any way. Category 1 is based upon high-level evidence; there is uniform NCCN consensus that the intervention is appropriate.¹

CMM¹=chronic myelomonocytic leukemia; MDS=myelodysplastic syndromes; NCCN=National Comprehensive Cancer Network.

IMPORTANT SAFETY INFORMATION

WARNING: DO NOT INTERCHANGE WITH OTHER DAUNORUBICIN AND/OR CYTARABINE-CONTAINING PRODUCTS

VYXEOS has different dosage recommendations than daunorubicin hydrochloride injection, cytarabine injection, daunorubicin citrate liposome injection, and cytarabine liposome injection. Verify drug name and dose prior to preparation and administration to avoid dosing errors.

Please see Important Safety Information on page 5 and full [Prescribing Information](#), including BOXED Warning.

Jazz Is Committed to Removing Barriers to Access and Reimbursement

JazzCares® supports healthcare providers and office staff with coverage and reimbursement support so appropriate patients can get access to VYXEOS and reduce their out-of-pocket costs.



JazzCares—Assists you with benefits investigations, prior authorizations and appeals, and referrals to financial assistance options for eligible patients



Savings Card—Eligible, commercially insured patients can pay as little as \$10 for their VYXEOS medication, subject to an annual maximum (restrictions apply)



Free Drug Program—Uninsured or underinsured patients who meet certain financial criteria may be eligible to receive VYXEOS at no cost^a

Your Jazz Oncology Business Manager provides expertise and support

- Assistance with reimbursement-related questions
- Purchasing, procurement, and distribution support, and education on coding and billing
- Click [here](#) to contact your Jazz Oncology Business Manager

^aSubject to financial and residency eligibility criteria. Terms and conditions apply.

Reimbursement information provided by Jazz Pharmaceuticals, Inc. is gathered from third-party sources and is presented for illustrative purposes only. This information does not constitute reimbursement or legal advice, and Jazz Pharmaceuticals, Inc. makes no representation or warranty regarding this information or its completeness, accuracy, or timeliness. Laws, regulations, and payer policies concerning reimbursement are complex and change frequently, and service providers are responsible for all decisions relating to coding and reimbursement submissions. Accordingly, Jazz Pharmaceuticals, Inc. strongly recommends that you consult with your payers, reimbursement specialist, and/or legal counsel regarding coding, coverage, and reimbursement matters.

Insurance coverage and plans may vary. JazzCares provides general information only and is not a guarantee of any coverage or reimbursement outcome. All treatment decisions rest solely with the treating physician or qualified healthcare professional. Jazz Pharmaceuticals, Inc. reserves the right to terminate or modify this program at any time with or without notice. Other terms and conditions apply.

Please see Important Safety Information on page 5 and full [Prescribing Information](#), including BOXED Warning.



Ordering Information

VYXEOS is available for purchase from the authorized Specialty Distributors listed below.

- Before ordering, verify your facility has an account by contacting one of the Specialty Distributors below
- For questions about product returns, your facility should also contact their Specialty Distributor

cencora

ASD Healthcare	Oncology Supply
Phone/Fax: (800) 746-6273/(800) 547-9413 Online: https://www.asdhealthcare.com/home	Phone/Fax: (800) 633-7555/(800) 248-8205 Online: https://www.oncologysupply.com



Cardinal Health

Phone/Fax: (877) 453-3972/(877) 274-9897 Online: Order Express (Hospitals) https://orderexpress.cardinalhealth.com Specialty Online (Clinics): https://specialtyonline.cardinalhealth.com

MCKESSON

McKesson Plasma and Biologics	McKesson Specialty Health
Phone/Fax: (877) 625-2566/(888) 752-7626 Online: https://connect.mckesson.com	Phone/Fax: (800) 482-6700/(800) 289-9285 Online: http://MSCS.McKesson.com

Group purchasing organizations (GPOs)

VYXEOS is available through the following GPOs	
<ul style="list-style-type: none">• ION Solutions (Cencora)• Onmark® GPO (McKesson)	<ul style="list-style-type: none">• Unity GPO (The US Oncology Network/McKesson)• VitalSource™ (Cardinal Health™)

Please see Important Safety Information on page 5 and full Prescribing Information, including BOXED Warning.

Vyxeos®
(daunorubicin and cytarabine) 44 mg/100 mg per vial
liposome for injection

Coding Information

Code Type	Code	Description
Inpatient/Outpatient Codes		
ICD-10-CM (inpatient and outpatient)	C92.0	AML
	C92.00	AML, not having achieved remission
	C92.01	AML, in remission
	C92.02	AML, in relapse
	C92.A	AML with multilineage dysplasia
	C92.A0	AML with multilineage dysplasia, not having achieved remission
	C92.A1	AML with multilineage dysplasia, in remission
	C92.A2	AML with multilineage dysplasia, in relapse
CPT (inpatient and outpatient)	96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
MS-DRG (inpatient only)	837	Chemotherapy with acute leukemia as SDX or with high-dose chemotherapy agent with MCC
	838	Chemotherapy with acute leukemia as SDX with CC or high-dose chemotherapy agent
	839	Chemotherapy with acute leukemia as SDX without CC/MCC
Billing Codes		
NDC	68727-745-01	Single-dose vial: 44 mg daunorubicin and 100 mg cytarabine (for billing purposes)
	68727-745-02	Carton (2 vials)
	68727-745-05	Carton (5 vials)
HCPCS J-code	J9153	Dosage: injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine Billing unit per dose: 1 Billing unit per vial: 44

JW modifier

Effective January 1, 2017, providers and suppliers are required to report the JW modifier on Medicare Part B drug claims for discarded drugs and biologicals not administered to the patient. The modifier shall only be used for drugs in single-dose or single-use packaging that are appropriately discarded. For more information, visit: www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf.

Additional VYXEOS reimbursement information

- For Medicare Fee-for-Service, the current reimbursement rate is the ASP plus 6%² (subject to change; for up-to-date ASP information, visit <https://www.cms.gov/medicare/payment/all-fee-service-providers/medicare-part-b-drug-average-sales-price/asp-pricing-files>)
- For other types of insurers, reimbursement rates may vary based on the type of health insurance plan and on your practice's contract with the individual health insurance plans

Contact provider services at your patient's health plan to determine the reimbursement rate for VYXEOS prior to billing, and make sure your system is updated to bill appropriately. For additional information on coding and billing, reimbursement support, or to review any issues you may be experiencing, please contact your Jazz Oncology Business Manager or JazzCares at 1-833-533-JAZZ (5299).

ASP=average sales price; CC=comorbid conditions; CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification;

MCC=major complication or comorbidity; MS-DRG=Medicare Severity Diagnosis Related Group;

NDC=National Drug Code; SDX=secondary diagnosis.

Please see Important Safety Information on page 5 and full Prescribing Information, including BOXED Warning.



For More Information

Visit
www.jazzcares.com/hcp/vyxeos
or
www.vyxeospro.com

Call the Patient Support Hotline at
(833) 533-5299, Monday – Friday,
8:00 AM – 8:00 PM ET

Contact Jazz Pharmaceuticals
Medical Information at
(800) 520-5568 or click [here](#)

IMPORTANT SAFETY INFORMATION (cont.)

- VYXEOS is contraindicated in patients with a history of serious hypersensitivity reactions to cytarabine, daunorubicin, or any component of the formulation.
- Serious or fatal hemorrhage events, including fatal CNS hemorrhages, associated with prolonged severe thrombocytopenia, have occurred in patients treated with VYXEOS. Monitor blood counts regularly and administer platelet transfusion support as required.
- VYXEOS contains daunorubicin, which has a known risk of cardiotoxicity. Assess cardiac function before, during, and after treatment as clinically indicated. Discontinue in patients with impaired cardiac function unless the benefit of treatment outweighs the risk. VYXEOS treatment is not recommended in patients with cardiac function that is less than normal. Calculate the lifetime cumulative anthracycline exposure prior to each cycle of VYXEOS. VYXEOS is not recommended in patients who have reached the maximum lifetime anthracycline dose limit.
- If a severe or life-threatening hypersensitivity reaction occurs, discontinue VYXEOS permanently, treat according to the standard of care, and monitor until signs and symptoms resolve.
- VYXEOS contains copper and has the potential to cause copper overload in patients with Wilson's disease or other copper-related metabolic disorders. Monitor patients and use only if the benefits outweigh the risks. Discontinue in patients with signs or symptoms of acute copper toxicity.
- Daunorubicin has been associated with severe local tissue necrosis at the site of drug extravasation. Administer VYXEOS by the intravenous route only. Confirm patency of intravenous access before administration.
- VYXEOS can cause fetal harm. Advise females and males of reproductive potential of the potential risk to a fetus and to use effective contraception.
- The most common adverse reactions (incidence $\geq 25\%$) are hemorrhagic events (74%), febrile neutropenia (70%), rash (56%), edema (55%), nausea (49%), mucositis (48%), diarrhea (48%), constipation (42%), musculoskeletal pain (43%), fatigue (39%), abdominal pain (36%), dyspnea (36%), headache (35%), cough (35%), decreased appetite (33%), arrhythmia (31%), pneumonia (31%), bacteremia (29%), chills (27%), sleep disorders (26%), and vomiting (25%).

Please see full [Prescribing Information](#), including BOXED Warning.

References: 1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for Acute Myeloid Leukemia V.6.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed October 24, 2023. To view the most recent and complete version of the guideline, go online to NCCN.org. 2. 42 CFR § 414.904 - Average sales price as the basis for payment. US Government Publishing Office. <https://www.govinfo.gov/content/pkg/CFR-2022-title42-vol3/pdf/CFR-2022-title42-vol3-sec414-904.pdf>. Accessed February 29, 2024.

VYXEOS is a registered trademark of Jazz Pharmaceuticals, Inc.



©2024 Jazz Pharmaceuticals plc or its subsidiaries
US-VYX-2100007 Rev0324

