

Corporate Medical Policy

Daunorubicin and Cytarabine (Vyxeos™)

File Name:	daunorubicin_and_cytarabine_vyxeos
Origination:	11/2017
Last CAP Review:	11/2018
Next CAP Review:	11/2019
Last Review:	11/2018

Description of Procedure or Service

Vyxeos™ is a liposomal combination of daunorubicin, an anthracycline topoisomerase inhibitor, and cytarabine, a nucleoside metabolic inhibitor that is indicated for the treatment of adults with newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC).

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for Daunorubicin and Cytarabine (Vyxeos) when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Daunorubicin and Cytarabine (Vyxeos) is covered

Daunorubicin and Cytarabine (Vyxeos) may be medically necessary when the following criteria are met:

- When used for the treatment of adults with newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC).

Use of Daunorubicin and Cytarabine (Vyxeos) may be considered medically necessary for clinical indications not listed above when the drug is prescribed for the treatment of cancer either:

- In accordance with FDA label (when clinical benefit has been established, see Policy Guidelines); **OR**
- In accordance with specific strong endorsement or support by nationally recognized compendia, when such recommendation is based on strong/high levels of evidence, and/or uniform consensus of clinical appropriateness has been reached.

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When Daunorubicin and Cytarabine (Vyxeos) is not covered

Daunorubicin and Cytarabine (Vyxeos) is considered not medically necessary when criteria under “When Daunorubicin and Cytarabine (Vyxeos) is covered” are not met.

Daunorubicin and Cytarabine (Vyxeos) is considered investigational when used for:

1. Non-cancer indications; **OR**
2. When criteria are not met regarding FDA labeling **OR** strong endorsement/support by nationally recognized compendia, as stated under “When Daunorubicin and Cytarabine (Vyxeos) is covered.”

Policy Guidelines

Drugs prescribed for treatment of cancer in accordance with FDA label may be considered medically necessary when clinical benefit has been established, and should not be determined to be investigational as defined in Corporate Medical Policy (CMP), “Investigational (Experimental) Services.”

Please refer to CMP “Investigational (Experimental) Services” for a summary of evidence standards from nationally recognized compendia.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: J9153, J3490, J3590, J9999, S0353, S0354

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209401s0001bl.pdf

Specialty Matched Consultant Advisory Panel 11/2018

Policy Implementation/Update Information

12/29/17 New policy developed. Daunorubicin and Cytarabine (Vyxeos) may be medically necessary when used for the treatment of adults with newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC). Reference added. CPT code C9024 added to Billing/Coding section. Notification 12/29/17 for effective date 3/29/18. (lpr)

12/14/18 Specialty Matched Consultant Advisory Panel review 11/28/2018. No change to policy intent. (krc)

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12/31/18 Added HCPCS code J9153 to Billing/Coding section and deleted code C9024 effective 1/1/19. (krc)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.