# Daunorubicin/Cytarabine Liposome for Injection (VYXEOS)
# Criteria for Use
# June 2019

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

*The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.*

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the *PBM INTERnet* or *PBM INTRAnet* site for further information.

## Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive daunorubicin/cytarabine liposome.

- ☐ Hypersensitivity to daunorubicin, cytarabine or any of its components
- ☐ Pregnancy (known pregnancy or positive pregnancy test) and/or actively breastfeeding
- ☐ Prior cumulative anthracycline exposure > 368 mg/m$^2$ daunorubicin or equivalent
- ☐ Class III or IV heart failure symptoms (NYHA staging system)
- ☐ Left Ventricular Ejection Fraction < 50% (via echo, MUGA, MRI, etc.)
- ☐ Uncontrolled infection
- ☐ History of Wilson's disease or another copper-metabolism disorder (see Issues for Consideration)
- ☐ Tbili > 2.0 mg/dL (unless with Gilbert's Syndrome); ALT or AST > 3x ULN
- ☐ Severe renal impairment or end-stage renal disease, defined as Clcr < 30 ml/min

## Inclusion Criteria

The answers to the following must be fulfilled to meet criteria:

- ☐ Diagnosis of therapy-related AML (t-AML) **OR**
- ☐ Diagnosis of AML with myelodysplasia-related changes (AML-MRC) **OR**
- ☐ Diagnosis of AML with antecedent MDS or CMML

**AND**

- ☐ Patient has not received treatment for newly-diagnosed t-AML, AML-MRC or with antecedent MDS or CMML
- ☐ Goals of care and role of Palliative Care Consult have been discussed and documented
- ☐ ECOG Performance Status 0-2

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For women of childbearing potential

- ☐ Pregnancy should be excluded prior to receiving daunorubicin/cytarabine liposome and the patient provided contraceptive counseling on potential risks vs. benefits of receiving daunorubicin/cytarabine liposome if patient were to become pregnant.
- ☐ Advise females of reproductive potential to use effective contraception during treatment and for at least 6 months after their last dose.
- ☐ Advise males with female partners of reproductive potential to use effective contraception during treatment and for at least 6 months after their last dose; in addition, advise males that fertility may be compromised.
- ☐ Advise women not to breastfeed during treatment and for at least 2 weeks after last dose.

## Dosage and Administration

- Refer to Product Information for dosing, dose modifications and administration details.
- Boxed warning: DO NOT INTERCHANGE WITH OTHER DAUNORUBICIN AND/OR CYTARABINE-CONTAINING PRODUCTS
- Antiemetic potential per ASCO Clinical Practice Guidelines 2017: moderate
- Use appropriate measure to prevent Tumor Lysis Syndrome (TLS).

## Monitoring

- Prior to induction, evaluate cardiac function, renal and liver function tests
- TLS parameters, for those at risk
- Prior to each consolidation cycle, evaluate cardiac function, CBC, renal and liver function tests
- Pregnancy test (in women of childbearing potential) at baseline

## Issues for Consideration

- Due to prolonged neutropenia expected following treatment, would provide standard antimicrobial prophylaxis for induction of acute leukemia.
- Consider risks vs. benefits in patients with Wilson's disease, as use in this population has not been studied.
- Concomitant cardiotoxic drugs may increase the risk of cardiotoxicity, therefore necessitating cardiac function assessment more frequently
- Concomitant hepatotoxicity drugs may affect liver function thereby increasing the toxicity of daunorubicin/cytarabine liposome and necessitating liver function assessment more frequently

## Discontinuation Criteria

- Signs or symptoms of acute copper toxicity
- Severe infusion reaction or any life-threatening hypersensitivity reaction
- Worsening cardiac function, unless benefit outweighs risk (consider cardiology consultation)
- Decline in ECOG performance status to level unacceptable to maintain quality of life

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