Regimen Reference Order

LEUK – DAUNOrubicin and cytarabine liposome (VYXEOS) Consolidation

ARIA: LEUK - [VYXEOS Consolidation]

Planned Course: **Every 35 days* (Days 1 and 3) for 2 cycles**
***Consolidation Cycle 1 is to begin 5 to 8 weeks after the start of the last Induction Cycle**
***Consolidation Cycle 2 is to begin 5 to 8 weeks after the start of Consolidation Cycle 1 in patients who do not show disease progression or unacceptable toxicity to VYXEOS®**

Indication for Use: **Therapy-Related Acute Myeloid Leukemia (t-AML) OR Acute Myeloid Leukemia with Myelodysplasia-Related Changes (AML-MRC), Newly Diagnosed**

CVAD: Preferred (VESICANT INVOLVED)

Proceed with treatment if:
ANC equal to or greater than 0.5 x 10^9/L AND Platelets equal to or greater than 50 x 10^9/L
- **Contact Leukemia/BMT (L/BMT) Physician if parameters not met**

SEQUENCE OF MEDICATION ADMINISTRATION

Pre-treatment Requirements

Drug	Dose	CCMB Administration Guideline
Not Applicable		

Treatment Regimen
LEUK – DAUNOrubicin and cytarabine liposome (VYXEOS®) Consolidation

Establish primary solution 500 mL of: normal saline

Drug	Dose	CCMB Administration Guideline
Days 1 and 3		
ondansetron	16 mg	Orally 30 minutes pre-chemotherapy
dexamethasone	12 mg	Orally 30 minutes pre-chemotherapy
DAUNOrubicin and cytarabine liposome (VYXEOS®)	29 mg/m^2 (based on DAUNOrubicin component)	IV in normal saline 500 mL over 90 minutes
All doses will be automatically rounded that fall within CCMB Approved Dose Bands. See Dose Banding document for more information		

In the event of an infusion-related hypersensitivity reaction, refer to the **'Hypersensitivity Reaction Standing Order'**

REQUIRED MONITORING

All Cycles

- CBC, serum creatinine, urea, liver enzymes, total bilirubin and uric acid as per Physician Orders
- Full vital signs (temperature, heart rate, respiratory rate, blood pressure and O_2 saturation) at baseline and as clinically indicated
- No observation period is required. Patient can be discharged from treatment room if stable whether they had a reaction or not

Cardiac Monitoring

- Left Ventricular Ejection Fraction (LVEF) at baseline, before Cycle 1 Consolidation and as clinically indicated

Recommended Support Medications

Drug	Dose	CCMB Administration Guideline
pegfilgrastim (brand name specific) *(See Filgrastim Clinical Guide)*	6 mg	Subcutaneous once on Day 8 **Alert: pegfilgrastim to be given as a single dose once per chemotherapy cycle no sooner than 24 hours after chemotherapy*
ciprofloxacin	500 mg	Orally every 12 hours starting Day 1 *Given until ANC greater than 0.5 x 10^9/L for 2 consecutive days*
valACYclovir	500 mg	Orally once daily starting Day 1 *Given until ANC greater than 0.5 x 10^9/L for 2 consecutive days*
dexamethasone	8 mg	Orally once daily on Days 2, 4 and 5
metoclopramide	10 – 20 mg	Orally every 4 hours as needed for nausea and vomiting

DISCHARGE INSTRUCTIONS

- Patients should be instructed to contact their cancer team immediately if symptoms of hypersensitivity reactions occur after discharge
- Instruct patient to continue taking anti-emetics at home
- Reinforce safe handling precautions of medications, blood and body fluids for 48 hours after completion of chemotherapy

ADDITIONAL INFORMATION

- Brand name VYXEOS® contains two drugs (liposomal DAUNOrubicin and liposomal cytarabine) in one IV dosage form
- VYXEOS® can cause severe, prolonged myelosuppression
- Serious or fatal infections and hemorrhagic events, including fatal CNS hemorrhages, have occurred in patients treated with VYXEOS®
- Cumulative doses of anthracycline/anthracenedione (e.g. epiRUBicin, DOXOrubicin, DAUNOrubicin, IDArubicin and mitoxantrone) should be calculated and assessed prior to each cycle of therapy. If exceeding recommended lifetime anthracycline dose thresholds and patient is benefiting from ongoing anthracycline therapy, adding dexrazoxane may be considered by the L/BMT Physician (see SUPP – dexrazoxane)
- Cumulative doses of DAUNOrubicin greater than 550 mg/m^2 (or 400 mg/m^2 in patients who received radiation therapy to the mediastinum) have been associated with an increased incidence of drug-induced congestive heart failure
- VYXEOS® contains copper gluconate. VYXEOS® should only be used in patients with a history of Wilson's disease or other copper-related disorders if the benefits outweigh the risks. Monitoring and consultation with a hepatologist and nephrologist may be required
- Administration site restrictions are in place for VYXEOS®. VYXEOS® should only be administered at CCMB MacCharles in Winnipeg