Regimen Reference Order

LEUK – gemtuzumab ozogamicin + HIDAC 18

ARIA: LEUK - [gemtuz ozogamicin + HIDAC 18]

Planned Course: **2 Cycles (1 cycle = 28 days)**
Indication for Use: **Consolidation for de novo Acute Myeloid Leukemia; CD33 positive; Favorable, Intermediate or Unknown Cytogenetics**
CVAD: At Provider's Discretion

Proceed with treatment if:
ANC equal to or greater than 1.5 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 – gemtuzumab ozogamicin + HIDAC 18

Establish primary solution 500 mL of: normal saline

Drug	Dose	CCMB Administration Guideline
Day 1		
cetirizine	10 mg	Orally **1 hour** prior to gemtuzumab ozogamicin
acetaminophen	650 mg	Orally **1 hour** prior to gemtuzumab ozogamicin
ondansetron	16 mg	Orally 30 minutes pre-chemotherapy
dexamethasone	12 mg	IV in normal saline 50 mL over 15 minutes **1 hour** prior to gemtuzumab ozogamicin **Nursing Alert: gemtuzumab ozogamicin starts **1 hour after completion** of dexamethasone infusion*
Wait 1 hour after completion of IV pre-medication(s) before starting gemtuzumab ozogamicin		
gemtuzumab ozogamicin	3 mg/m^2 **Maximum dose is 4.5 mg**	IV in normal saline 50 mL over 2 hours *Use 0.2 or 0.22 micron filter* *Note: Doses less than 3.9 mg must be prepared for administration by syringe* **Nursing Alert: cytarabine infusion starts after observation period is complete (if required)*
cytarabine	3000 mg/m^2	IV in normal saline 500 mL over 3 hours

Days 2 to 6		
dexamethasone	12 mg	Orally 30 minutes pre-chemotherapy
ondansetron	16 mg	Orally 30 minutes pre-chemotherapy
cytarabine	3000 mg/m^2	IV in normal saline 500 mL over 3 hours

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

REQUIRED MONITORING

EKG monitoring
- At baseline within 1 week of starting therapy

All Cycles
- Weight assessment by clinic prior to Day 1 then weekly for 3 weeks
- Handwriting protocol during cytarabine therapy
- Complete nursing assessment prior to each dose of chemotherapy

Day 1 (gemtuzumab ozogamicin monitoring)
- Full vital signs (temperature, heart rate, respiratory rate, blood pressure and O_2 saturation) at baseline and as clinically indicated
- If no infusion-related reactions, no observation period is required
- If reaction occurs, observe patient for 1 hour after completion of gemtuzumab ozogamicin
- Full vital signs at end of observation period

Leukemia Consolidations Instructions
- Transfuse 2 units packed red blood cells each over 1 to 3 hours as tolerated for hemoglobin less than 80 g/L
- Transfuse 1 adult dose platelets over 1 hour for platelet count less than 10 x 10^9/L or if platelet count less than 50 x 10^9/L and patient is bleeding
- Day 1 blood work – CBC with differential, serum creatinine, urea, Na, K, Cl, CO2, glucose, Ca, Phos, Mg, total bilirubin, protein, albumin, uric acid, AST, ALT, ALP, GGT and LDH
- Day 8 and onwards blood work – Daily CBC with differential, serum creatinine, urea, Na, K, Cl, CO2 and glucose until counts recover. On Monday and Thursday add Ca, Phos, Mg, total bilirubin, protein, albumin, uric acid, AST, ALT, ALP, GGT and LDH until counts recover
- Type and screen: Monday and Thursday
- If serum creatinine doubles from pre-treatment level, 24-hour urine for creatinine clearance and urinalysis every Monday
- Notify physician if patient experiences a single oral temperature of equal to or greater than 38.3°C or greater than 38°C lasting at least one hour; follow Febrile Neutropenia (FNE) protocol

Special Instructions

1. These orders are to be used only for leukemia patients
2. Book 4-hour treatment slot for potential transfusion of blood products / supportive therapy on chemotherapy Days 8 through 20
3. Document blood products on Cumulative Blood Product Administration Assessment Record

Febrile Neutropenia Instructions

1. Blood cultures:
   a) Draw 10 mL aliquot of blood for aerobic cultures from each lumen of the central line plus one peripheral site and one 10 mL aliquot for anaerobic cultures from same peripheral site,
   OR
   b) If an indwelling central line is not in situ, draw 20 mL aliquot of blood for aerobic and anaerobic cultures (10 mL into each) from one peripheral site and one 10 mL aliquot for aerobic cultures from a second peripheral site
2. Stat complete blood count (CBC) and differential
3. Serum Na, K, Cl, total CO2, serum creatinine, urea, glucose, total bilirubin, AST, ALT, ALP, GGT and LDH
4. Chest X-ray (PA and lateral views)
5. Panorex/sinus X-rays/abdominal X-rays where appropriate symptoms and signs indicate a focus
6. Swab of any lesion or site of potential infection for C&S, fungal and viral cultures as indicated
7. Midstream urine (MSU) for C&S
8. Stool for Clostridium difficile toxin, enteric pathogens (C&S) and enteric virus detection where appropriate if patient has diarrhea
9. Skin biopsies or skin scrapings where indicated
10. Consult primary hematologist/oncologist

Nursing history and physical assessment to include:

a. Day of most recent cycle of cytotoxic therapy
b. Day of cycle on which FNE occurred
c. Concurrent antimicrobial therapy
d. Potential site of infection - respiratory tract (upper including sinuses, ears and nasopharynx & lower including lungs, trachea, bronchi and pleural spaces)
e. Skin (central line, biopsy sites and rashes)
f. Gastrointestinal tract (oropharynx and esophagus - including dysphagia and odynophagia; abdomen - bowel sounds and tenderness; perirectal tissues)
g. Genitourinary
h. CNS

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*
allopurinol*	300 mg	Orally once daily on Days 1 to 10 inclusive **ONLY FOR PATIENTS WITH ELEVATED SERUM URIC ACID*
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*
prednisoLONE 1% eye drops	2 drops	Instill 2 drops into each eye every 4 hours while awake beginning the morning that cytarabine starts and continue until 48 hours after the last dose of cytarabine
metoclopramide	10 – 20 mg	Orally every 4 hours as needed for nausea and vomiting

DISCHARGE INSTRUCTIONS

- Patients should be instructed to contact the L/BMT physician on call immediately if symptoms of hypersensitivity reactions occur after discharge
- Remind patient to take support medications at home
- cytarabine can cause conjunctivitis. Remind patient to instill prednisoLONE eye drops until 48 hours after the last dose of cytarabine. If patient continues to have signs and symptoms of conjunctivitis, then please contact prescribing hematologist for further instructions
- Reinforce safe handling precautions of medications, blood and body fluids for 48 hours after completion of chemotherapy

ADDITIONAL INFORMATION

- cytarabine can cause mental confusion
- This protocol is intended for patients age less than 60 years old
- For dosing calculations use the patient's actual body weight
- Pharmacare application to be completed
- Consider adjusting cytarabine dose for renal dysfunction