Regimen Reference Order – LEUK - blinatumomab

ARIA: LEUK – [blinatumomab]

Planned Course: **Induction (Cycles 1, 2 and 3) and Consolidation (Cycles 4 and 5): 28 days of treatment (continuous infusion) followed by 14 days with no therapy (1 cycle = 42 days)**

Indication for Use: **Acute Lymphoblastic Leukemia**

Alert: Protocol is restricted to adult patients greater than or equal to 45 kg

CVAD: Required

Proceed with treatment if:

- ***AST/ALT is less than 5 times the upper limit of normal***
- ***Total bilirubin is less than 3 times the upper limit of normal***
- ***Creatinine Clearance greater than 30 mL/min***

Proceed regardless of platelet or ANC

- **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 - blinatumomab

Drug	Dose	CCMB Administration Guideline
Cycle 1 Induction		
Days 1 to 9		
Patients will be admitted to hospital for treatment. Follow inpatient orders		
Days 10, 12, 14, 16, 18, 20, 22, 24, 26		
blinatumomab	56 mcg (28 mcg/day)	IV in normal saline continuously over 48 hours by ambulatory infusion device to start at 1130H *CADD SOLIS VIP settings:* *Infusion rate = 5 mL/hour* *Reservoir Volume = 240 mL* **Nursing Alert*: *Change bag exactly every 48 hours. Discard remainder of solution in IV bag and IV line*

Day 28		
blinatumomab	28 mcg	IV in normal saline continuously over 24 hours by ambulatory infusion device to start at 1130H *CADD SOLIS VIP settings:* ***Infusion rate = 10 mL/hour*** *Reservoir Volume = 240 mL* ****Alert**: Dose in bag and infusion rate for Cycle 1, Day 28 are different from all other days of cycle* **Nursing Alert*: *Discard remainder of solution in IV bag and IV line on Day 29 at 11:30H*
Cycle 2 Induction		
Days 1 to 2		
Patients will be admitted to hospital for treatment. Follow inpatient orders		
Days 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27		
blinatumomab	56 mcg (28 mcg/day)	IV in normal saline continuously over 48 hours by ambulatory infusion device to start at 1130H *CADD SOLIS VIP settings:* *Infusion rate = 5 mL/hour* *Reservoir Volume = 240 mL* **Nursing Alert*: *Change bag exactly every 48 hours. Discard remainder of solution in IV bag and IV line on Day 29 at 11:30H*
Cycles 3 Induction		
Day 1		
dexamethasone	20 mg	IV in normal saline 50 mL over 15 minutes **1 hour** prior to blinatumomab **Nursing Alert: blinatumomab starts **1 hour after completion** of dexamethasone infusion*
acetaminophen	650 mg	Orally 30 minutes prior to blinatumomab
diphenhydrAMINE	50 mg	IV in normal saline 50 mL over 15 minutes
blinatumomab	56 mcg (28 mcg/day)	IV in normal saline continuously over 48 hours by ambulatory infusion device to start at 1130H *CADD SOLIS VIP settings:* *Infusion rate = 5 mL/hour* *Reservoir Volume = 240 mL* **Nursing Alert*: *Change bag exactly every 48 hours. Discard remainder of solution in IV bag and IV line*
Days 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27		
blinatumomab	56 mcg (28 mcg/day)	IV in normal saline continuously over 48 hours by ambulatory infusion device to start at 1130H *CADD SOLIS VIP settings:* *Infusion rate = 5 mL/hour* *Reservoir Volume = 240 mL* **Nursing Alert*: *Discard remainder of solution in IV bag and IV line on Day 29 at 11:30H*

Cycles 4 to 5 Consolidation		
Day 1		
dexamethasone	20 mg	IV in normal saline 50 mL over 15 minutes **1 hour** prior to blinatumomab **Nursing Alert*: *blinatumomab starts **1 hour after completion** of dexamethasone infusion*
acetaminophen	650 mg	Orally 30 minutes prior to blinatumomab
diphenhydrAMINE	50 mg	IV in normal saline 50 mL over 15 minutes
blinatumomab	56 mcg (28 mcg/day)	IV in normal saline continuously over 48 hours by ambulatory infusion device to start at 1130H *CADD SOLIS VIP settings:* *Infusion rate = 5 mL/hour* *Reservoir Volume = 240 mL* **Nursing Alert*: *Change bag exactly every 48 hours. Discard remainder of solution in IV bag and IV line*
Days 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, 25, 27		
blinatumomab	56 mcg (28 mcg/day)	IV in normal saline continuously over 48 hours by ambulatory infusion device to start at 1130H *CADD SOLIS VIP settings:* *Infusion rate = 5 mL/hour* *Reservoir Volume = 240 mL* **Nursing Alert*: *Discard remainder of solution in IV bag and IV line on Day 29 at 11:30H*
If re-initiation of therapy after interruptions of 4 hours of more, hospitalization or observation is recommended		

Do NOT flush line when drug running. May result in a bolus of blinatumomab. If accessing lumen, withdraw 2 mL of blood (containing drug) first, and then flush.

In the event of an infusion-related hypersensitivity reaction, contact Leukemia/BMT physician on call

REQUIRED MONITORING

Throughout therapy

- Monitor for signs and symptoms of cytokine release syndrome (CRS). Serious adverse events that may be associated with CRS include: pyrexia, headache, nausea, asthenia, hypotension, and elevations in serum aminotransferases and bilirubin
- Monitor for signs and symptoms of neurotoxicity. Symptoms may include: trembling, disturbance or loss of movement of parts of the body, speech or coordination disorders, apraxia, dizziness, confusion, disorientation, reversible seizures, encephalopathy, somnolence, agitation
- Full vital signs (temperature, heart rate, respiratory rate, blood pressure and O_2 saturation) as clinically indicated

Cycle 1 with each 48 hour bag change

- CBC, differential, creatinine, urea, electrolytes, LDH, bilirubin, uric acid, phosphate, calcium, AST, ALT, ALP, GGT, albumin as per Physician Orders

Cycle 2 and onwards

Weekly

- CBC, creatinine, urea, electrolytes, LDH, bilirubin, uric acid, phosphate, calcium, AST, ALT, ALP, GGT, albumin as per Physician Orders

Twice weekly

- lipase

Recommended Support Medications

Drug	Dose	CCMB Administration Guideline
Not Applicable		

DISCHARGE INSTRUCTIONS

- Advise patient to contact L/BMT physician on call if encounter problems with pump after hours

ADDITIONAL INFORMATION

- This protocol only applies to patients greater than or equal to 45 kg