Regimen Reference Order – LEUK – blinatumomab (MRD positive)

ARIA: LEUK – [blinatumomab MRD+]

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

Indication for Use: **Acute Lymphoblastic Leukemia, Minimal Residual Disease (MRD) positive**

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

CVAD: Required (Ambulatory Pump)

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 of limit of normal***
- ***Creatinine clearance is greater than 30 mL/minute***

Proceed with treatment regardless of platelet or ANC values

- **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 (MRD positive)

Drug	Dose	CCMB Administration Guideline
Cycle 1 Induction		
Days 1 and 3		
Patients will be admitted to hospital for treatment. Follow inpatient orders. Note that Day 1 and Day 3 are ordered as 48-hour infusions via ambulatory infusion starting at 1130h		
Days 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* *Use non-DEHP bags and non-DEHP administration sets with 0.2 or 0.22 micron in-line filter* **Nursing Alert: Change bag exactly every 48 hours. Discard remainder of solution in IV bag and IV line on Day 29 at 1130h* **Nursing Alert: IV tubing is primed with blinatumomab*

Cycle 2 Consolidation		
Day 1		
Patients will be admitted to hospital for treatment. Follow inpatient orders Note that Day 1 is ordered as a 48-hour infusion via ambulatory infusion starting at 1130h		
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 <u>over 48 hours</u> by ambulatory infusion device to start at 1130h *CADD SOLIS VIP settings:* *Infusion rate = 5 mL/hour* *Reservoir Volume = 240 mL* *Use non-DEHP bags and non-DEHP administration sets with 0.2 or 0.22 micron in-line filter* **Nursing Alert: Change bag exactly every 48 hours. Discard remainder of solution in IV bag and IV line on Day 29 at 1130h* **Nursing Alert: IV tubing is primed with blinatumomab*
Cycles 3 and 4 Consolidation		
Day 1		
cetirizine	10 mg	Orally 30 minutes prior to blinatumomab
acetaminophen	650 mg	Orally 30 minutes prior to blinatumomab
dexamethasone	20 mg	IV in normal saline 50 mL over 15 minutes **<u>1 hour</u>** prior to blinatumomab **Nursing Alert: blinatumomab starts **1 hour after completion** of dexamethasone infusion*
Wait 1 hour after completion of IV pre-medications before starting blinatumomab		
blinatumomab	56 mcg (28 mcg/day)	IV in normal saline continuously <u>over 48 hours</u> by ambulatory infusion device to start at 1130h *CADD SOLIS VIP settings:* *Infusion rate = 5 mL/hour* *Reservoir Volume = 240 mL* *Use non-DEHP bags and non-DEHP administration sets with 0.2 or 0.22 micron in-line filter* **Nursing Alert: Change bag exactly every 48 hours. Discard remainder of solution in IV bag and IV line* **Nursing Alert: IV tubing is primed with blinatumomab*
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 <u>over 48 hours</u> by ambulatory infusion device to start at 1130h *CADD SOLIS VIP settings:* *Infusion rate = 5 mL/hour* *Reservoir Volume = 240 mL* *Use non-DEHP bags and non-DEHP administration sets with 0.2 or 0.22 micron in-line filter*

		**Nursing Alert: Change bag exactly every 48 hours. Discard remainder of solution in IV bag and IV line on Day 29 at 1130h* **Nursing Alert: IV tubing is primed with blinatumomab*
If re-initiating therapy after interruption of 4 hours or more, hospitalization or observation is recommended		

Do NOT flush line when drug is running. This 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 and agitation
- Full vital signs (temperature, heart rate, respiratory rate, blood pressure and O_2 saturation) as clinically indicated

Cycle 1

Each 48-hour bag change

- CBC with differential, serum creatinine, urea, electrolytes including phosphate and calcium, AST, ALT, Alkaline phosphatase, LDH, GGT, total bilirubin, uric acid and albumin as per Physician Orders

Twice weekly

- lipase

Cycles 2 to 4

Weekly

- CBC with differential, serum creatinine, urea, electrolytes including phosphate and calcium, AST, ALT, Alkaline phosphatase, LDH, GGT, total bilirubin, uric acid and albumin as per Physician Orders

Twice weekly

- lipase

Recommended Support Medications

Drug	Dose	CCMB Administration Guideline
None required		

DISCHARGE INSTRUCTIONS

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

ADDITIONAL INFORMATION

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