

## Regimen Reference Order CLL – fludarabine (IV) + riTUXimab

ARIA: CLL – [FR (IV)]

Planned Course: Every 28 days for 6 cycles

Indication for Use: Chronic Lymphocytic Leukemia

CVAD: At Provider’s Discretion

**Proceed with treatment if:**

- Creatinine clearance greater than 30 mL/minute

**Cycle 1**

- Proceed with treatment regardless of CBC

**Cycle 2 onwards**

- ANC equal to or greater than  $1 \times 10^9/L$  AND Platelets equal to or greater than  $50 \times 10^9/L$ 
  - ❖ Contact Hematologist if parameters not met

### Pre-treatment Requirements

Drug	Dose	CCMB Administration Guideline
allopurinol*	300 mg	Orally once daily for 10 days to begin 3 days prior to Cycle 1 and at provider’s discretion for subsequent cycles <b>(Self-administered at home)</b> *Only patients at risk of tumor lysis syndrome will be prescribed allopurinol

### Treatment Regimen – CLL – fludarabine (IV) + riTUXimab

Establish primary solution 500 mL of: normal saline		
Drug	Dose	CCMB Administration Guideline
<b>Cycle 1</b>		
<b>Day 1</b>		
cetirizine	10 mg	Orally 30 minutes prior to riTUXimab
acetaminophen	650 mg	Orally 30 minutes prior to riTUXimab
dexamethasone	40 mg	IV in normal saline 50 mL over 15 minutes
<b>Wait 30 minutes after completion of IV pre-medications before starting riTUXimab</b>		
riTUXimab (IV brand name specific)	375 mg/m <sup>2</sup>	<b>Slow infusion:</b> IV made up to a final concentration of 1 mg/mL in normal saline. Start at 50 mg/hr for 60 minutes and escalate infusion rate in 50 mg/hr increments every 30 minutes to maximum of 400 mg/hr <i>*Nursing Alert: IV tubing is primed with riTUXimab</i> <i>*Alert: Ensure brand name on prescription label (indicated in brackets on prescription label) matches prescribed order</i> <i>*Alert: Pharmacy to ensure final volume on label</i>

fludarabine	25 mg/m <sup>2</sup>	IV in normal saline 50 mL over 30 minutes
<b>Days 2 to 5</b>		
fludarabine	25 mg/m <sup>2</sup>	IV in normal saline 50 mL over 30 minutes
<b>Cycle 2 onwards</b>		
<b>Day 1</b>		
cetirizine	10 mg	Orally 30 minutes prior to riTUXimab
acetaminophen	650 mg	Orally 30 minutes prior to riTUXimab
dexamethasone	40 mg	IV in normal saline 50 mL over 15 minutes
<b>Wait 30 minutes after completion of IV pre-medications before starting riTUXimab</b>		
riTUXimab (Subcutaneous)	1400 mg (1400 mg = 11.7 mL)	<b>Subcutaneous:</b> Administer <b>over 5 minutes</b> into abdomen Syringe should be held in hand for 5 minutes to warm up and decrease viscosity Use 25G needle <i>*Nursing Alert: Ensure subcutaneous riTUXimab formulation is used</i>
<b>OR</b>		
riTUXimab (IV brand name specific)	375 mg/m <sup>2</sup>	<b>Rapid infusion:</b> IV in normal saline over 90 minutes: Infuse 50 mL of a 250 mL bag (or 100 mL of a 500 mL bag) over 30 minutes, then infuse the remaining 200 mL (or 400 mL of a 500 mL bag) over 60 minutes <i>Concentration dependent drug. Pharmacy will adjust diluent volume to ensure drug stability</i> <i>*Alert: Ensure brand name on prescription label (indicated in brackets on prescription label) matches prescribed order</i> <i>*Alert: Pharmacy to ensure final volume on label</i>
fludarabine	25 mg/m <sup>2</sup>	IV in normal saline 50 mL over 30 minutes
<b>Days 2 to 5</b>		
fludarabine	25 mg/m <sup>2</sup>	IV in normal saline 50 mL over 30 minutes
All doses will be automatically rounded that fall within the DSG Approved Dose Bands. See LYMP DSG – 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

Day 1

- CBC, serum creatinine, urea, electrolytes, liver enzymes, LDH, total bilirubin, uric acid and albumin as per Physician Orders

**INTRAVENOUS riTUXimab**

- Full vital signs (temperature, heart rate, respiratory rate, blood pressure and O<sub>2</sub> saturation) at baseline and as clinically indicated
- No observation period is required after riTUXimab administration. Patient can be discharged from treatment room if stable whether they had a reaction or not

**SUBCUTANEOUS riTUXimab**

- Full vital signs (temperature, heart rate, respiratory rate, blood pressure and O<sub>2</sub> saturation) at baseline, at discharge, and as clinically indicated
- **15 minute observation period required after each dose**

**Recommended Support Medications**

Drug	Dose	CCMB Administration Guideline
valACYclovir	500 mg	Orally once daily
sulfamethoxazole-trimethoprim	800/160 mg	Orally twice daily on Saturdays and Sundays only
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-emetic(s) and support medications at home
- valACYclovir is prescribed for herpes zoster (shingles) prophylaxis
- sulfamethoxazole-trimethoprim DS is prescribed for *Pneumocystis jirovecii* pneumonia prophylaxis
- Reinforce applicable safe handling precautions of medications, blood and body fluids for 48 hours after completion of chemotherapy

**ADDITIONAL INFORMATION**

- Administering nurse must document any infusion-related reactions with any dose of riTUXimab
- Ensure there were no Grade 3 or 4 infusion-related reaction with the previous dose prior to administering riTUXimab via Subcutaneous injection or Rapid Infusion
- Patients on fludarabine should receive irradiated blood products
- valACYclovir and sulfamethoxazole-trimethoprim DS continue while on treatment and for 6 months after discontinuation of FR due to risk of prolonged immunosuppression
- Intravenous riTUXimab formulation is available from more than one manufacturer and uses several different brand names. Brand name will be indicated in brackets after riTUXimab. **Ensure prescription label matches the brand name on prescribed order for intravenous riTUXimab**