Regimen Reference Order

LYMP – riTUXimab + cladribine (Hairy Cell Leukemia)

ARIA: LYMP – [riTUXimab + cladribine (HCL)]

Planned Course: **riTUXimab and cladribine once weekly for 6 weeks, followed by riTUXimab once weekly for 2 weeks**

Indication for Use: **Hairy Cell Leukemia**

CVAD: At Provider's Discretion

Proceed with treatment if:

Day 1

- ***Proceed regardless of blood counts***

Days 8, 15, 22, 29 and 36 (riTUXimab and cladribine)

- ***ANC and platelets are the same or greater than pre-treatment value (prior to Day 1)***

Day 43 and 50 (riTUXimab)

- ***ANC and platelets are the same or greater than pre-treatment value (prior to Day 1)***
  - ❖ **Contact Hematologist if parameters not met**

Note: ***Hepatitis B serology results must be reviewed in accordance with CCMB Policy Hepatitis B Monitoring for Oncology and Hematology Patients***

SEQUENCE OF MEDICATION ADMINISTRATION

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 **(Self-administered at home)** Only patients at risk of tumor lysis syndrome will be prescribed allopurinol

Treatment Regimen – riTUXimab + cladribine (Hairy Cell Leukemia)

Establish primary solution 500 mL of: normal saline

Drug	Dose	CCMB Administration Guideline
Day 1		
cetirizine	10 mg	Orally 30 minutes prior to riTUXimab
acetaminophen	650 mg	Orally 30 minutes prior to riTUXimab
dexamethasone	20 mg	IV in normal saline 50 mL over 15 minutes
Wait 30 minutes after completion of IV pre-medication(s) before starting riTUXimab		

riTUXimab (IV brand name specific)	375 mg/m^2	**<u>Slow infusion</u>: (if greater than 6 months since last riTUXimab dose or no previous riTUXimab):** 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 a maximum of 400 mg/hr **Nursing Alert: IV tubing is primed with riTUXimab* **Alert: Ensure brand name on prescription label (indicated in brackets on prescription label) matches prescribed order* **Alert: Pharmacy to ensure final volume on label*
		OR
		<u>Slow infusion</u>: (if equal to or less than 6 months since last riTUXimab dose): IV made up to a final concentration of 1 mg/mL in normal saline. Start at 100 mg/hr for 30 minutes and escalate infusion rate in 100 mg/hr increments every 30 minutes to a maximum of 400 mg/hr **Nursing Alert: IV tubing is primed with riTUXimab* **Alert: Ensure brand name on prescription label (indicated in brackets on prescription label) matches prescribed order* **Alert: Pharmacy to ensure final volume on label*
cladribine	0.14 mg/kg	IV in normal saline 500 mL over 2 hours
Days 8, 15, 22, 29 and 36		
cetirizine	10 mg	Orally 30 minutes prior to riTUXimab
acetaminophen	650 mg	Orally 30 minutes prior to riTUXimab
dexamethasone	12 mg	Orally 30 minutes prior to riTUXimab
riTUXimab (IV brand name specific)	375 mg/m^2	**<u>Rapid infusion</u>**: 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 **Alert: Ensure brand name on prescription label (indicated in brackets on prescription label) matches prescribed order* **Alert: Pharmacy to ensure final volume on label*
		OR
		<u>Slow infusion</u>: IV made up to a final concentration of 1 mg/mL in normal saline. Start at 100 mg/hr for 30 minutes and escalate infusion rate in 100 mg/hr increments every 30 minutes to a maximum of 400 mg/hr **Nursing Alert: IV tubing is primed with riTUXimab* **Alert: Ensure brand name on prescription label (indicated in brackets on prescription label) matches prescribed order* **Alert: Pharmacy to ensure final volume on label*
		OR

riTUXimab (Subcutaneous)	1400 mg (1400 mg = 11.7 mL)	**Subcutaneous:** Administer over 5 minutes into abdomen Syringe should be held in hand for 5 minutes to warm up and decrease viscosity Use 25G needle **Alert:* ***Platelets must be greater than 50 x 10^9/L*** *when using the subcutaneous route of administration* **Nursing Alert: Ensure subcutaneous riTUXimab formulation is used (riTUXimab-hyaluronidase, human)*
cladribine	0.14 mg/kg	IV in normal saline 500 mL over 2 hours
Days 43 and 50		
cetirizine	10 mg	Orally 30 minutes prior to riTUXimab
acetaminophen	650 mg	Orally 30 minutes prior to riTUXimab
dexamethasone	12 mg	Orally 30 minutes prior to riTUXimab
riTUXimab (IV brand name specific)	375 mg/m^2	**Rapid infusion**: 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 **Alert: Ensure brand name on prescription label (indicated in brackets on prescription label) matches prescribed order* **Alert: Pharmacy to ensure final volume on label*
		OR
		Slow infusion: IV made up to a final concentration of 1 mg/mL in normal saline. Start at 100 mg/hr for 30 minutes and escalate infusion rate in 100 mg/hr increments every 30 minutes to a maximum of 400 mg/hr **Nursing Alert: IV tubing is primed with riTUXimab* **Alert: Ensure brand name on prescription label (indicated in brackets on prescription label) matches prescribed order* **Alert: Pharmacy to ensure final volume on label*
	OR	
riTUXimab (Subcutaneous)	1400 mg (1400 mg = 11.7 mL)	**Subcutaneous:** Administer over 5 minutes into abdomen Syringe should be held in hand for 5 minutes to warm up and decrease viscosity Use 25G needle **Alert:* ***Platelets must be greater than 50 x 10^9/L*** *when using the subcutaneous route of administration* **Nursing Alert: Ensure subcutaneous riTUXimab formulation is used (riTUXimab-hyaluronidase, human)*
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

Hepatitis B serology
- Hepatitis B surface antigen and Hepatitis B core antibody (drawn within preceding 5 years)

Baseline
- HIV serology

Days 1, 8, 15, 22, 29 and 36
- CBC, serum creatinine, urea, liver enzymes and uric acid as per Physician Orders

Days 43 and 50
- CBC

INTRAVENOUS riTUXimab
- Full vital signs (temperature, heart rate, respiratory rate, blood pressure and O_2 saturation) prior to each dose 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

SUBCUTANEOUS riTUXimab
- Full vital signs (temperature, heart rate, respiratory rate, blood pressure and O_2 saturation) prior to each dose, at discharge and as clinically indicated
- **15-minute observation period required after each dose**

Recommended Support Medications

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

ADDITIONAL INFORMATION

- Due to the risk of reactivation of Hepatitis B virus (HBV) while on this treatment regimen, prescriber must adhere to CCMB Policy ***Hepatitis B Monitoring for Oncology and Hematology Patients*** for ordering and interpreting HBV serology and prescribing antiviral prophylaxis
- Administering nurse must document any infusion-related reactions with any dose of riTUXimab
- Ensure there were **no Grade 3 or 4** infusion-related reactions with any previous dose prior to administering riTUXimab via subcutaneous injection or rapid infusion
- 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**
- valacyclovir and sulfamethoxazole-trimethoprim continue while on treatment and for 3 months after discontinuation of treatment due to risk of prolonged immunosuppression
- Patients on cladribine require irradiated blood products