Regimen Reference Order – CLL – iBRUtinib

ARIA: CLL – [iBRUtinib]

Planned Course: **Once daily until disease progression or unacceptable toxicity (1 Cycle = 30 days)**
Indication for Use: **Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)**

Proceed with treatment if:
ANC equal to or greater than 0.5 x 10^9/L AND Platelets equal to or greater than 50 x 10^9/L

- **Contact Physician if parameters not met**

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 Only patients at risk of tumor lysis syndrome will be prescribed allopurinol

Treatment Regimen – CLL – iBRUtinib

Drug	Dose	CCMB Administration Guideline
iBRUtinib	420 mg	Orally once daily (with or without food)
iBRUtinib (IMBRUVICA®) available dosage strength: 140 mg capsule **Classification: Cytotoxic, Hazardous**		

REQUIRED MONITORING

Baseline

- CBC, serum creatinine, urea, electrolytes, liver enzymes, LDH, total bilirubin, uric acid and albumin as per Physician Orders
- Hepatitis B serology
- Molecular profile (IgHV, TP53 and FISH)
- EKG
- Full vital signs (temperature, heart rate, respiratory rate, blood pressure and O_2 saturation)

Weeks 1, 4, 8 and 12 and at every clinic visit thereafter (at least every 3 months)

- CBC, serum creatinine, urea, electrolytes, liver enzymes, LDH, total bilirubin, uric acid and albumin as per Physician Orders
- Monitor blood pressure and heart rate for tachycardia
- At physician's discretion, EKG to assess for atrial fibrillation if tachycardia or irregular rhythm present

Recommended Support Medications

Drug	Dose	CCMB Administration Guideline
None required		

INSTRUCTIONS FOR PATIENT

- Patients should notify clinic prior to starting any new medication. iBRUtinib has potential for drug-drug interactions
- Avoid grapefruit and grapefruit juice, Seville oranges (i.e. orange marmalade) and starfruit
- Patient should report signs and symptoms of bleeding (i.e. excess bleeding), palpitations, syncope, and skin or nail changes
- Reinforce applicable safe handling precautions of medications, blood and body fluids while on iBRUtinib

ADDITIONAL INFORMATION

- Lymphocytosis is expected with therapy and will not be considered evidence of disease progression unless accompanied by other clinical signs of disease progression (i.e. increasing lymphadenopathy, constitutional symptoms, etc.)
- Hematologist should be consulted regarding dosing of iBRUtinib pre- and post-surgery for patients undergoing a surgical procedure, including dental surgery, due to risk of bleeding regardless of platelet count