Regimen Reference Order – LEUK – gilteritinib

ARIA: LEUK – [gilteritinib]

Planned Course: **Once daily until disease progression or unacceptable toxicity (1 cycle = 30 days)**
Indication for Use: **Acute Myeloid Leukemia; Relapsed or Refractory; FLT3 mutation positive**

Proceed with treatment if:
Blood work at provider's discretion: not required to proceed with treatment

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 start of gilteritinib and at provider's discretion for additional duration **(Self-administered at home)** * Only patients at risk of tumor lysis syndrome will be prescribed allopurinol

Treatment Regimen – LEUK – gilteritinib

Drug	Dose	CCMB Administration Guideline
gilteritinib	120 mg	Orally once daily with or without food Swallow whole **(Self-administered at home)**
gilteritinib (Xospata®) available dosage strength: 40 mg tablet **Classification: Cytotoxic, Hazardous**		

REQUIRED MONITORING

Baseline

- CBC, serum creatinine, urea, electrolytes, liver enzymes, lipase and Creatine Kinase (CK) as per Physician Orders
- EKG
- Weight

Cycle 1

- Every week: CBC, serum creatinine, urea, electrolytes, liver enzymes, lipase and Creatine Kinase (CK) as per Physician Orders
- EKG Days 8 and 15
- Weight prior to cycle

Cycle 2

- Every other week: CBC, serum creatinine, urea, electrolytes, liver enzymes, lipase and Creatine Kinase (CK) as per Physician Orders
- EKG prior to cycle
- Weight prior to cycle

Cycle 3

- Prior to cycle: CBC, serum creatinine, urea, electrolytes liver enzymes, lipase and Creatine Kinase (CK) as per Physician Order
- EKG prior to cycle
- Weight prior to cycle

Cycle 4 and onwards

- Prior to each cycle: CBC, serum creatinine, urea, electrolytes, liver enzymes, lipase and Creatine Kinase (CK) as per Physician Orders
- EKG as clinically indicated
- Weight prior to each cycle

Recommended Support Medications

Drug	Dose	CCMB Administration Guideline
None required		

DISCHARGE INSTRUCTIONS

- Patients should be encouraged to maintain adequate hydration
- Patients should notify clinic prior to starting any new medication. gilteritinib has potential for drug-drug interactions
- Avoid grapefruit and grapefruit juice, Seville oranges (i.e. orange marmalade) and starfruit
- Patient should notify clinic if they experience fever, shortness of breath, swelling of arms and legs, irregular heartbeat, chest pain, abdominal pain, headache, changes to vision, fainting, confusion or rash while on treatment
- Reinforce applicable safe handling precautions of medications, blood and body fluids while on gilteritinib

ADDITIONAL INFORMATION

- gilteritinib can prolong QT interval
- gilteritinib can cause serious toxicities such as differentiation syndrome, posterior reversible encephalopathy and pancreatitis
- Patients who will undergo allogeneic stem cell transplant should stop their gilteritinib one week prior to the administration of the conditioning regimen and can be resumed 30 or greater days after stem cell transplant if engraftment is successful, and the patient does not have grade 2 or greater acute graft versus host disease and is in composite complete remission
- gilteritinib will be dispensed by CancerCare Manitoba Pharmacy