

Regimen Reference Order

MYEL – isatuximab + pomalidomide + dexamethasone

ARIA: MYEL - [isatuximab + pom + dex]

Planned Course: Until disease progression or unacceptable toxicity (1 cycle = 28 days)

Indication for Use: Multiple Myeloma Relapsed/Refractory

CVAD: At Provider's Discretion

Proceed with treatment if:

pomalidomide:

Day 1 of every cycle & Day 15 of Cycles 1 and 2

- ***ANC equal to or greater than $1 \times 10^9/L$ AND Platelets equal to or greater than $30 \times 10^9/L$***

isatuximab:

- ***On Day 1, proceed with isatuximab only when pomalidomide starts***
 - ***On subsequent treatment days, proceed with isatuximab regardless of CBC***
- ❖ **Contact Hematologist if parameters not met**

SEQUENCE OF MEDICATION ADMINISTRATION

Pre-treatment Requirements

Drug	Dose	CCMB Administration Guideline
montelukast	10 mg	Orally once daily in the morning for 5 days starting the day before the first dose of isatuximab montelukast may be prescribed prior to subsequent isatuximab doses at physician's discretion (Self-administered at home) <i>*Nursing Alert: Notify physician if patient has not taken montelukast. montelukast is prescribed to prevent infusion reactions</i>

Treatment Regimen – MYEL – isatuximab + pomalidomide + dexamethasone

Establish primary solution 500 mL of: normal saline

Drug	Dose	CCMB Administration Guideline
Cycle 1		
acetaminophen	975 mg	Orally <u>1 hour</u> prior to isatuximab on Days 1, 8, 15 and 22
famotidine	40 mg	Orally <u>1 hour</u> prior to isatuximab on Days 1, 8, 15 and 22
cetirizine	20 mg	Orally <u>1 hour</u> prior to isatuximab on Days 1, 8, 15 and 22
dexamethasone	40 mg	IV in normal saline 50 mL over 15 minutes <u>1 hour</u> prior to isatuximab on Days 1, 8, 15 and 22 <i>*Nursing Alert: isatuximab starts at least 1 hour after completion of dexamethasone infusion</i>

Wait 1 hour after completion of IV pre-medication(s) before starting isatuximab

isatuximab	10 mg/kg	<p>IV in normal saline 250 mL on Day 1 following administration rates below:</p> <ul style="list-style-type: none"> • 0 to 60 minutes – 25 mL/hour • 60 to 90 minutes – 50 mL/hour • 90 to 120 minutes – 75 mL/hour • 120 to 150 minutes – 100 mL/hour • 150 to 180 minutes – 125 mL/hour • 180 minutes onwards – 150 mL/hour <p>Use 0.2 or 0.22 micron filter</p> <p>*Alert: Pharmacy to ensure final volume in bag = 250 mL</p> <p>*Nursing Alert: IV tubing is primed with isatuximab</p>
	10 mg/kg	<p>IV in normal saline 250 mL on Day 8 following administration rates below:</p> <ul style="list-style-type: none"> • 0 to 30 minutes – 50 mL/hour • 30 to 60 minutes – 100 mL/hour • 60 minutes onwards – 200 mL/hour <p>Use 0.2 or 0.22 micron filter</p> <p>*Alert: Pharmacy to ensure final volume in bag = 250 mL</p> <p>*Nursing Alert: IV tubing is primed with isatuximab</p>
	10 mg/kg	<p>IV in normal saline 250 mL over 75 minutes on Days 15 and 22</p> <p>Use 0.2 or 0.22 micron filter</p> <p>*Alert: Pharmacy to ensure final volume in bag = 250 mL</p> <p>*Nursing Alert: IV tubing is primed with isatuximab</p>
pomalidomide	4 mg	<p>Orally once daily on Days 1 to 21, then 7 days off</p> <p>Take with or without food. Swallow whole</p> <p>(Self-administered at home)</p>
Cycle 2 and Onwards		
dexamethasone	40 mg	<p>Orally once daily in the morning with food on Days 1, 8, 15 and 22</p> <p>(Self-administered at home)</p>
acetaminophen	975 mg	Orally 1 hour prior to isatuximab on Days 1 and 15
famotidine	40 mg	Orally 1 hour prior to isatuximab on Days 1 and 15
cetirizine	10 mg	Orally 1 hour prior to isatuximab on Days 1 and 15
isatuximab	10 mg/kg	<p>IV in normal saline 250 mL over 75 minutes on Days 1 and 15</p> <p>Use 0.2 or 0.22 micron filter</p> <p>*Alert: Pharmacy to ensure final volume in bag = 250 mL</p> <p>*Nursing Alert: IV tubing is primed with isatuximab</p>
pomalidomide	4 mg	<p>Orally once daily on Days 1 to 21, then 7 days off</p> <p>Take with or without food. Swallow whole</p> <p>(Self-administered at home)</p>
All doses will be automatically rounded that fall within CCMB Approved Dose Bands. See Dose Banding document for more information		
<p>pomalidomide (POMALYST®) available dosage strengths: 1 mg, 2 mg, 3 mg and 4 mg capsules</p> <p>Classification: Cytotoxic, Hazardous</p>		

In the event of an infusion-related hypersensitivity reaction, refer to the 'Hypersensitivity Reaction Standing Order'

REQUIRED MONITORING

Baseline

- RBC serology (genotyping) mandatory prior to starting isatuximab
- Hepatitis B serology

Cycle 1 (also see isatuximab monitoring below)

Day 1

- CBC, serum creatinine, urea, electrolytes, liver enzymes, total bilirubin, albumin and glucose as per Physician Orders
- TSH prior to Cycle 1 then every 3 cycles thereafter as per Physician Orders
- Serum Protein Electrophoresis (SPEP)/Free Light Chain Ratio (FLCH) (response assessment)

Day 15

- CBC

Days 8 and 22

- No blood work required

Cycle 2

Day 1

- CBC, serum creatinine, urea, electrolytes, liver enzymes, total bilirubin, albumin and glucose as per Physician Orders
- SPEP/FLCH (response assessment)

Day 15

- CBC

Cycle 3 and Onwards

Day 1

- CBC, serum creatinine, urea, electrolytes, liver enzymes, total bilirubin, albumin and glucose as per Physician Orders
- SPEP/FLCH (response assessment)
- TSH every 3 cycles as per Physician Orders

Day 15

- No blood work required

isatuximab monitoring

- Full vital signs (temperature, heart rate, respiratory rate, blood pressure and O₂ saturation) at baseline and as clinically indicated
- No observation period is required after isatuximab administration. Patient can be discharged from treatment room if stable whether they had a reaction or not

Per RevAid Program – See Additional Information

- Patients of childbearing potential require β HCG according to RevAid Program requirements

Recommended Support Medications

Drug	Dose	CCMB Administration Guideline
valACYclovir	500 mg	Orally once daily
acetylsalicylic acid (ASA) enteric coated	81 mg delayed release	Orally once daily
fluticasone and salmeterol combination	100 mcg – 50 mcg per dose	Prescribed at physician's discretion If patient has a history of asthma or COPD, 1 inhalation twice daily only as needed post isatuximab infusion

DISCHARGE INSTRUCTIONS

- Patients should be instructed to contact their cancer team immediately if symptoms of hypersensitivity reactions occur after discharge
- pomalidomide and dexamethasone are cancer therapies in this treatment regimen. Remind patient to take pomalidomide and dexamethasone at home
- Instruct patient to take recommended support medications at home
- Reinforce applicable safe handling precautions of medications, blood and body fluids for 48 hours after completion of pomalidomide

ADDITIONAL INFORMATION

- isatuximab interferes with cross-matching and red blood cell antibody screening. **Indicate on all Canadian Blood Services requisitions that the patient is on isatuximab**
- isatuximab may interfere with the interpretation of the Serum Protein Electrophoresis (SPEP) results. **Indicate on all immunology (SPEP) requisitions that the patient is on isatuximab**
- Administering nurse must document any infusion-related reactions with any dose of isatuximab
- Consideration may be given to reducing dexamethasone dose at the physician's discretion to 20 mg for patients age 75 years or older
- Patients should take therapy to prevent blood clots while on pomalidomide. The majority of patients will be prescribed acetylsalicylic acid (ASA) enteric coated 81 mg once daily. Patients at high risk may be prescribed other anticoagulants instead of acetylsalicylic acid
- All patients should be considered for bisphosphonate therapy
- pomalidomide is teratogenic
- Patients of childbearing potential will require monthly pregnancy tests (β HCG) that must be done within 7 days of the next prescription fill
- pomalidomide is controlled by a distribution program requiring prescriptions to be written by a RevAid registered physician and dispensed by a RevAid registered pharmacy
- pomalidomide can only be given to patients who are registered in and meet all conditions of the RevAid Program