

## Regimen Reference Order

### MYEL – isatuximab + pomalidomide + dexamethasone

**ARIA: MYEL - [isatuximab + pomalidomide + 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 each isatuximab dose of <b>Cycle 1</b> Cycle 2 onwards at the discretion of the physician <b>(Self-administered at home)</b> <i>*Nursing Alert: Notify physician if patient has not taken montelukast</i>

#### Treatment Regimen – MYEL – isatuximab + pomalidomide + dexamethasone

Establish primary solution 500 mL of: normal saline

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

diphenhydrAMINE	50 mg	IV in normal saline 50 mL over 15 minutes <b>1 hour</b> prior to isatuximab on <b>Days 1, 8, 15 and 22</b>
isatuximab	10 mg/kg	IV in normal saline 250 mL on <b>Day 1</b> following administration rates below: <ul style="list-style-type: none"> <li>• 0 to 60 minutes – 25 mL/hour</li> <li>• 60 to 90 minutes – 50 mL/hour</li> <li>• 90 to 120 minutes – 75 mL/hour</li> <li>• 120 to 150 minutes – 100 mL/hour</li> <li>• 150 to 180 minutes – 125 mL/hour</li> <li>• 180 minutes onwards – 150 mL/hour</li> </ul> Use 0.2 or 0.22 micron filter <i>*Alert: Pharmacy to ensure final volume in bag = 250 mL</i> <i>*Nursing Alert: IV tubing is primed with isatuximab</i>
	10 mg/kg	IV in normal saline 250 mL on <b>Day 8</b> following administration rates below: <ul style="list-style-type: none"> <li>• 0 to 30 minutes – 50 mL/hour</li> <li>• 30 to 60 minutes – 100 mL/hour</li> <li>• 60 minutes onwards – 200 mL/hour</li> </ul> Use 0.2 or 0.22 micron filter <i>*Alert: Pharmacy to ensure final volume in bag = 250 mL</i> <i>*Nursing Alert: IV tubing is primed with isatuximab</i>
	10 mg/kg	IV in normal saline 250 mL over 75 minutes on <b>Days 15 and 22</b> Use 0.2 or 0.22 micron filter <i>*Alert: Pharmacy to ensure final volume in bag = 250 mL</i> <i>*Nursing Alert: IV tubing is primed with isatuximab</i>
pomalidomide	4 mg	Orally once daily with or without food on <b>Days 1 to 21, then 7 days off</b> Swallow whole <b>(Self-administered at home)</b>
<b>Cycle 2 and Onwards</b>		
acetaminophen	975 mg	Orally <b>1 hour</b> prior to isatuximab on <b>Days 1 and 15</b>
famotidine	40 mg	Orally <b>1 hour</b> prior to isatuximab on <b>Days 1 and 15</b>
dexamethasone	40 mg	IV in normal saline 50 mL over 15 minutes <b>1 hour</b> prior to isatuximab on <b>Days 1 and 15</b> <i>*Nursing Alert: isatuximab starts 1 hour after completion of dexamethasone</i>
diphenhydrAMINE	50 mg	IV in normal saline 50 mL over 15 minutes <b>1 hour</b> prior to isatuximab on <b>Days 1 and 15</b>
isatuximab	10 mg/kg	IV in normal saline 250 mL over 75 minutes on <b>Days 1 and 15</b> Use 0.2 or 0.22 micron filter <i>*Alert: Pharmacy to ensure final volume in bag = 250 mL</i> <i>*Nursing Alert: IV tubing is primed with isatuximab</i>

pomalidomide	4 mg	Orally once daily with or without food on <b>Days 1 to 21, then 7 days off</b> Swallow whole <b>(Self-administered at home)</b>
dexamethasone	40 mg	Orally once daily in the morning with food on <b>Days 8 and 22</b> <b>(Self-administered at home)</b>

**pomalidomide (Pomalyst®) available dosage strengths: 1 mg, 2 mg, 3 mg and 4 mg capsules**  
**Classification: Cytotoxic, Hazardous**

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

#### Day 1

- CBC, serum creatinine, urea, electrolytes, liver enzymes, total bilirubin, albumin and glucose 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)

#### Day 15

- No blood work required

### Throughout therapy

- TSH every 3 months as per Physician Orders

### isatuximab monitoring

#### Cycle 1, Day 1

- Full vital signs (temperature, heart rate, respiratory rate, blood pressure and O<sub>2</sub> saturation)
  - at baseline, then
  - blood pressure and heart rate every 15 minutes for 1 hour, then
  - blood pressure and heart rate every 30 minutes for 1 hour, then
  - blood pressure and heart rate every hour until infusion complete

**isatuximab monitoring (continued)**

## Subsequent Doses

- Full vital signs (temperature, heart rate, respiratory rate, blood pressure and O<sub>2</sub> saturation) at baseline and then as clinically indicated

## Observation Periods

- No observation period 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  $\beta$ 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
salmeterol and fluticasone combination	50 mcg - 100 mcg per dose	Prescribed at physician's discretion If patient has a history of asthma or COPD, inhale 1 puff twice daily only as needed post infusion

**DISCHARGE INSTRUCTIONS**

- 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
- 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
- Patients of childbearing potential will require monthly pregnancy tests ( $\beta$ HCG) that must be done within 7 days of the next prescription fill
- Administration site restrictions are in place for isatuximab. Cycle 1, Days 1 and 8 must be administered at CCMB MacCharles in Winnipeg