# 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 x $10^9$/L AND Platelets equal to or greater than 30 x $10^9$/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**

***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 |
|---|---|---|
| Not Applicable | | |

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

**Establish primary solution 500 mL of: normal saline**

| Drug | Dose | CCMB Administration Guideline |
|---|---|---|
| **Cycle 1** | | |
| montelukast | 10 mg | Orally **1 hour** prior to isatuximab on **Day 1 ONLY** |
| acetaminophen | 975 mg | Orally **1 hour** prior to isatuximab on **Days 1, 8, 15 and 22** |
| famotidine | 40 mg | Orally **1 hour** prior to isatuximab on **Days 1, 8, 15 and 22** |
| cetirizine | 20 mg | Orally **1 hour** prior to isatuximab on **Days 1, 8, 15 and 22** |
| dexamethasone | 40 mg | IV in normal saline 50 mL over 15 minutes **1 hour** prior to isatuximab on **Days 1, 8, 15 and 22**<br>**Nursing Alert:* *isatuximab starts **at least 1 hour after completion** of dexamethasone infusion* |

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

| | | |
|---|---|---|
| isatuximab | 10 mg/kg | IV in normal saline 250 mL on **Day 1** following administration rates below:<br>• 0 to 60 minutes – 25 mL/hour<br>• 60 to 90 minutes – 50 mL/hour<br>• 90 to 120 minutes – 75 mL/hour<br>• 120 to 150 minutes – 100 mL/hour<br>• 150 to 180 minutes – 125 mL/hour<br>• 180 minutes onwards – 150 mL/hour<br>*Use 0.2 or 0.22 micron filter*<br>**Alert:* *Pharmacy to ensure final volume in bag = 250 mL*<br>**Nursing Alert:* *IV tubing is primed with isatuximab* |
| | 10 mg/kg | IV in normal saline 250 mL on **Day 8** following administration rates below:<br>• 0 to 30 minutes – 50 mL/hour<br>• 30 to 60 minutes – 100 mL/hour<br>• 60 minutes onwards – 200 mL/hour<br>*Use 0.2 or 0.22 micron filter*<br>**Alert:* *Pharmacy to ensure final volume in bag = 250 mL*<br>**Nursing Alert:* *IV tubing is primed with isatuximab* |
| | 10 mg/kg | IV in normal saline 250 mL over 30 minutes on **Days 15 and 22**<br>*Use 0.2 or 0.22 micron filter*<br>**Alert:* *Pharmacy to ensure final volume in bag = 250 mL* |
| pomalidomide | 4 mg | Orally once daily on **Days 1 to 21**, followed by 7 days off<br>Take with or without food. Swallow whole<br>**(Self-administered at home)** |
| **Cycle 2 and Onwards** | | |
| dexamethasone | 40 mg | Orally once daily in the morning with food on **Days 1, 8, 15 and 22**<br>**(Self-administered at home)** |
| 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 | IV in normal saline 250 mL over 30 minutes on **Days 1 and 15**<br>*Use 0.2 or 0.22 micron filter*<br>**Alert:* *Pharmacy to ensure final volume in bag = 250 mL* |
| pomalidomide | 4 mg | Orally once daily on **Days 1 to 21**, followed by 7 days off<br>Take with or without food. Swallow whole<br>**(Self-administered at home)** |
| All doses will be automatically rounded that fall within CCMB Approved Dose Bands. See Dose Banding document for more information | | |
| **pomalidomide (POMALYST®) available dosage strengths: 1 mg, 2 mg, 3 mg and 4 mg capsules**<br>**Classification: Cytotoxic, Hazardous** | | |

**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
- RBC serology (genotyping) mandatory prior to starting isatuximab

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 $O_2$ 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 Reddy2Assist Program or RevAid – See Additional Information
- Patients of childbearing potential require βHCG according to Reddy2Assist or 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<br>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
- 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
- All patients should be considered for bisphosphonate therapy
- pomalidomide is teratogenic
- Patients of childbearing potential will require monthly pregnancy tests (βHCG) that must be done within 7 days of the next prescription fill
- Patients need to be enrolled in the Reddy2Assist or RevAid Program. pomalidomide can only be given to patients who are registered with and meet all conditions of the Reddy2Assist or RevAid Program
- pomalidomide will be dispensed by CCMB Pharmacy