PROTOCOL CODE: UMYISAPOMD (cycle 1)

A BC Cancer "Compassionate Access Program" request form must be completed and approved prior to treatment

Patient RevAid ID:_____

DOCTOR'S ORDERS

Ht _____cm Wt _____kg BSA_____m^2

REMINDER: Please ensure drug allergies and previous bleomycin are documented on the Allergy & Alert Form

DATE: **To be given:** **Cycle # 1**

Date of Previous Cycle: _____

Risk Category: ☐ **Female of Childbearing Potential (FCBP) Rx valid for 7 days**

Risk Category: ☐ **Male or Female of non-Childbearing Potential (NCBP)**

****Ensure Red Blood Cell Phenotype **and Group and Screen** for all patients prior to Cycle 1****

☐ Delay treatment _____ week(s)

☐ **CBC & Diff**, **platelets** day of treatment

Proceed with all medications for entire cycle as written, if within 96 hours of Day 1: **ANC greater than or equal to 1.0 x 10^9/L, platelets greater than or equal to 50 x 10^9/L and eGFR or creatinine clearance as per protocol**

Dose modification for: ☐ **Hematology: _____** ☐ **Other Toxicity: _____**

Proceed with treatment based on blood work from _____

POMALIDOMIDE

One cycle = 28 days

☐ **pomalidomide*_____mg** po daily, in the evening, on Days 1 to 21 and off for 7 days

☐ **pomalidomide* _____ mg** po _____

(*available as 4 mg, 3 mg, 2 mg, 1 mg capsules)

***Note: Use one capsule strength for the total dose; there are cost implications as costing is per capsule and not weight based**

☐ FCBP dispense 21 capsules (1 cycle)

☐ For Male and Female NCBP: Mitte: 21 capsules (1 cycle).

Physician to ensure DVT prophylaxis in place: ☐ ASA, ☐ Warfarin, ☐ low molecular weight heparin, ☐ direct oral anticoagulant or ☐ none (select one)

Pharmacy Use for Pomalidomide dispensing:

RevAid confirmation number:

_____

Pomalidomide lot number:

_____

Pharmacist counsel (initial):

_____

Special Instructions

DOCTOR'S SIGNATURE:

Physician Revaid ID:

SIGNATURE:

UC:

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STEROID: (select one)* RN to use patient's therapeutic steroid as pre-med for isatuximab.

30 minutes prior to isatuximab infusion:

dexamethasone 40 mg ☐ PO or ☐ IV in 50 mL NS over 15 minutes before isatuximab on Days 1, 8, 15 and 22

OR

dexamethasone 20 mg ☐ PO or ☐ IV in 50 mL NS over 15 minutes before isatuximab on Days 1, 8, 15 and 22

OR

☐ **predniSONE 100 mg** PO before isatuximab on Days 1, 8, 15, and 22

OR

☐ **hydrocortisone 100 mg** IV before isatuximab on Days 1, 8, 15, and 22

***Refer to Protocol for suggested dosing options**

ISATUXIMAB

- Per physician's clinical judgement, physician to ensure prophylaxis with valACYclovir 500 mg PO daily

ISATUXIMAB PREMEDICATIONS: Patient to take own supply. RN/Pharmacist to confirm.

30 minutes prior to isatuximab infusion:

dexamethasone or alternative steroid as ordered in steroid section

montelukast 10 mg PO prior to isatuximab on Day 1

☐ **montelukast 10 mg** PO prior to isatuximab on Days 8, 15 and 22

acetaminophen 650 mg PO prior to each isatuximab. Repeat **acetaminophen 650 mg** PO every 4 hours when needed if IV infusion exceeds 4 hours

Select one of the following:

☐ **loratadine 10 mg** PO prior to each isatuximab, then **diphenhydrAMINE 50 mg** IV every 4 hours when needed for isatuximab reaction

OR

☐ **diphenhydrAMINE 50 mg** ☐ PO or ☐ IV prior to each isatuximab. Repeat **diphenhydrAMINE 50 mg** IV every 4 hours when needed for isatuximab reaction

Optional (recommended for first isatuximab dose, see protocol):

☐ **famotidine 20 mg** IV in NS 100 mL over 15 minutes (Y-site compatible with diphenhydrAMINE, if using) on Day 1

☐ **famotidine 20 mg** IV in NS 100 mL over 15 minutes (Y-site compatible with diphenhydrAMINE, if using) on Days 8, 15, and 22

DOCTOR'S SIGNATURE:	**SIGNATURE:** **UC:**

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****Have Hypersensitivity Reaction Tray and Protocol Available****

ISATUXIMAB

CYCLE 1, Day 1:

isatuximab 10 mg/kg x _____ kg = _____mg **IV in 250 mL NS (use 0.2 micron in-line filter)**

Infusion rate for Day 1:

Start at 25 mL/hour. If no infusion-related reactions after 60 minutes, increase by 25 mL/hour every 30 minutes to a maximum rate of 150 mL/hour

If BP falls to less than 80/50 mmHg or pulse increases to greater than 120 or if flushing, dyspnea, chills, rash, pruritus, vomiting, chest pain, throat tightness, cough, wheezing, or any other new acute discomfort occurs, stop isatuximab infusion and page physician.

Vitals monitoring and observation:
Vital signs immediately before the start of infusion, then every 30 minutes x 4, then every 1 to2 hours until the end of infusion and at 30 minutes post infusion. Observe patient for 30 minutes after isatuximab infusion.

CYCLE 1, Day 8:

isatuximab 10 mg/kg x _____ kg = _____mg **IV in 250 mL NS (use 0.2 micron in-line filter)**

Infusion rate: Physician to determine rate of infusion

If no reaction in the previous infusion or reaction is Grade 2 or less:

☐ Start at 50 mL/hour. If no infusion-related reactions after 30 minutes, increase by 50 mL/hour for 30 minutes, then by 100 mL/hour until maximum 200 mL/hour

OR

If reaction in the previous infusion is Grade 3:

☐ Start at 25 mL/hour. If no infusion-related reactions after 60 minutes, increase by 25 mL/hour every 30 minutes to a maximum rate of 150 mL/hour.

Vitals monitoring and observation:
Vital signs immediately before the start, at the end of the infusion and as needed. Observe patient for 30 minutes after infusion

DOCTOR'S SIGNATURE:	**SIGNATURE:** **UC:**

DATE:

****Have Hypersensitivity Reaction Tray and Protocol Available****

ISATUXIMAB continued

CYCLE 1, Days 15 and 22:

isatuximab 10 mg/kg x _____ kg = _____mg **IV in 250 mL NS (use 0.2 micron in-line filter)**

Infusion rate for Days 15 and 22: Physician to determine rate of infusion

If no reaction in the previous infusion or reaction is Grade 2 or less:

☐ Infuse at 200 mL/hour.

OR

If reaction in the previous infusion is Grade 3:

☐ Start at 100 mL/hour. If no infusion-related reactions after 60 minutes, increase by 50 mL/hour every 60 minutes to a maximum rate of 200 mL/hour.

Vitals monitoring and observation:

Vital signs immediately before the start, at the end of the infusion and as needed. Observe patient for 30 minutes after infusion (Vitals and observation post-infusion not required after 3 treatments with no reaction).

OPTIONAL CYCLOPHOSPHAMIDE:

☐ **cyclophosphamide 500 mg** PO once weekly in the morning on Days 1, 8, 15 and 22. Dispense 1 cycle.

OR

☐ **cyclophosphamide** _____ **mg** PO once weekly in the morning on Days _____ Dispense 1 cycle.

OR

☐ **cyclophosphamide 50 mg** PO once in the morning every 2 days for 14 doses. Dispense 1 cycle.

DOCTOR'S SIGNATURE:	**SIGNATURE:** **UC:**

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RETURN APPOINTMENT ORDERS	
For Cycle 1, book chemo on Days 1, 8, 15 and 22 For Cycle 2 book chemo on Days 1 and 15 ☐ Return in **four** weeks for Doctor and Cycle 2	
CBC & Diff, platelets, creatinine, urea, sodium, potassium, total bilirubin, ALT, alkaline phosphatase, calcium, albumin, LDH, random glucose, serum protein electrophoresis *and* serum free light chain levels every 4 weeks **TSH every three months** (i.e. prior to cycles 4, 7, 10, 13, 16 etc) ☐ **Urine protein electrophoresis** every 4 weeks ☐ **Immunoglobulin panel (IgA, IgG, IgM)** every 4 weeks ☐ **Beta-2 microglobulin** every 4 weeks ☐ **CBC & Diff, platelets** on Days 8, 15, 22 ☐ **Creatinine, sodium, potassium** on Days 8, 15, 22 ☐ **Total bilirubin, ALT, alkaline phosphatase** on Days 8, 15, 22 ☐ **Random glucose** on Days 8, 15, 22 ☐ **Calcium, albumin** on Days 8, 15, 22 ☐ **Quantitative beta-hCG blood test for FCBP** 7-14 days and 24 h prior to cycle 1 and every week for 4 weeks during cycle 1 ☐ **Quantitative beta-hCG blood test for FCBP,** every 4 weeks, less than or equal to 7 days prior to the next cycle ☐ **Other tests** ☐ **Consults:** ☐ **See general orders sheet for additional requests**	
DOCTOR'S SIGNATURE:	**SIGNATURE:** **UC:**