



Provincial Health Services Authority

Information on this form is a guide only. User will be solely responsible for verifying its currency and accuracy with the corresponding BC Cancer treatment protocols located at www.bccancer.bc.ca and according to acceptable standards of care

PROTOCOL CODE: UMYDARBD (Cycle 1)

(Page 1 of 4)

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

DOCTOR'S ORDERS

Ht _____ cm Wt _____ kg BSA _____ m²

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

DATE:

To be given:

Cycle #: 1

****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 bortezomib dose day 1 as written, if within 96 hours (or within 48 hours for day15) **ANC greater than or equal to $0.5 \times 10^9/L$, platelets greater than or equal to $30 \times 10^9/L$, bilirubin less than or equal to 1.5 x upper limit of normal**
- Proceed with cyclophosphamide dose (if using) as written, for entire cycle, if day 1 lab is within 96 hours **ANC greater than or equal to $1.0 \times 10^9/L$, platelets greater than or equal to $80 \times 10^9/L$ and CrCl greater than or equal to 10 mL/min**
- Proceed with daratumumab day 1 dose as written, if within 96 hours (or within 48 hours for day15) **ANC greater than or equal to $1.0 \times 10^9/L$, platelets greater than or equal to $50 \times 10^9/L$**

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

Proceed with treatment based on blood work from _____

CHEMOTHERAPY:

CYCLOPHOSPHAMIDE

cyclophosphamide **300 mg/m²/day** x BSA x (_____ %) = _____ mg PO weekly on days 1, 8, 15 of a 28 day cycle (maximum dose 500 mg and round to nearest 25 mg)

BORTEZOMIB

- If patient is VZV seropositive and/or at physician's clinical judgement, physician to ensure prophylaxis with valACYclovir 500 mg daily while on bortezomib and/or daratumumab and for four weeks after discontinuation

bortezomib **1.3 mg/m²** or **1 mg/m²** or **0.7 mg/m²** (select one) x BSA = _____ mg

SC injection **weekly** on days 1, 8, 15 and 22

DOCTOR'S SIGNATURE:

SIGNATURE:

UC:



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(Page 2 of 4)

DATE:

STEROID: RN to use patient's therapeutic steroid as pre-med for daratumumab - refer to protocol.

Standard Regimen: daratumumab full dose administered on Cycle 1 Day 1

dexamethasone 40 mg or 20 mg PO before daratumumab on days 1, 8, 15 and 22

OR

predniSONE 100 mg PO before daratumumab on days 1, 8, 15, and 22

OR

Alternative Regimen: daratumumab split dose administered on Cycle 1 Day 1 and Day 2

dexamethasone 20 mg PO before daratumumab on days 1 and 2, and 40 mg before daratumumab on days 8, 15, 22

OR

dexamethasone 20 mg PO before daratumumab on days 1 and 2 and 20 mg before daratumumab on days 8, 15, 22

OR

predniSONE 50 mg PO before daratumumab on days 1 and 2, and prednisone 100 mg before daratumumab on days 8, 15, 22

Have Hypersensitivity Reaction Tray and Protocol Available

DARATUMUMAB

If patient is VZV seropositive and/or at physician's clinical judgement, physician to ensure prophylaxis with valACYclovir 500 mg daily while on bortezomib and/or daratumumab and for 4 weeks after discontinuation

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

dexamethasone as ordered in steroid section

montelukast 10 mg PO prior to daratumumab on Day 1 (and Day 2 if on alternative regimen)

montelukast 10 mg PO prior to daratumumab on Days 8, 15 and 22

acetaminophen 650 mg PO prior to each daratumumab. Repeat acetaminophen every 4 hours x 1 dose during infusion on day 1 of cycle 1 only, then every 4 hours when needed for fever

Select one of the following:

diphenhydramine 50 mg PO or IV prior to each daratumumab. Repeat diphenhydramine 50 mg PO or IV every 4 hours x 1 dose during the infusion on day 1 of cycle 1 only, then diphenhydrAMINE 50 mg IV every 4 hours when needed

OR

loratadine 10mg PO prior to each daratumumab, then diphenhydrAMINE 50 mg IV every 4 hours when needed

DOCTOR'S SIGNATURE:

**SIGNATURE:
UC:**

PROTOCOL CODE: UMYDARBD (Cycle 1)
(Page 3 of 4)

DATE:	
Have Hypersensitivity Reaction Tray and Protocol Available	
Standard regimen: daratumumab full dose administered on Cycle 1 Day 1	
<input type="checkbox"/> CYCLE 1, Day 1:	
daratumumab (First dose) 16 mg/kg x _____ kg = _____ mg IV in 1000 mL NS (use 0.2 micron in-line filter)	
OR	
Alternative regimen: daratumumab split dose administered on Cycle 1 Day 1 and Day 2	
<input type="checkbox"/> CYCLE 1, Days 1 and 2	
daratumumab 8 mg/kg x _____ kg = _____ mg IV in 500 mL NS (use 0.2 micron in-line filter)	
Infusion rate for Day 1, (and Day 2, if Alternative regimen):	
Start at 50 mL/h. If no infusion-related reactions after 60 minutes, increase by 50 mL/h every 60 minutes to a maximum rate of 200 mL/h	
If BP falls to less than 80/50 mmHg or pulse increases to greater than 120 or if flushing, dyspnea, chills, rash, pruritis, vomiting, chest pain, throat tightness, cough, wheezing, or any other new acute discomfort occurs, stop daratumumab infusion and page physician.	
Vitals monitoring:	
Vital signs immediately before the start of infusion, then every 30 minutes x 4, then every 1-2 hours until the end of infusion and at 30 minutes post infusion. Observe patient for 30 minutes after each daratumumab infusion.	
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CYCLE 1, Day 8:	
daratumumab 16 mg/kg x _____ kg = _____ mg IV in 500 mL NS (use 0.2 micron in-line filter)	
Infusion rate: Physician to determine rate of infusion	
<i>If no reaction in the previous infusion or reaction is Grade 2 or less:</i>	
<input type="checkbox"/> Start at 200 mL/h. If no infusion-related reactions after 30 minutes, infuse the remainder at 450 mL/h (Rapid infusion)	
OR	
<i>If reaction in the previous infusion is Grade 3:</i>	
<input type="checkbox"/> Start at 50 mL/h. If no infusion-related reactions after 60 minutes, increase by 50 mL/h every 60 minutes to a maximum rate of 200 mL/h (Slow Infusion).	
Vitals monitoring:	
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:

PROTOCOL CODE: UMYDARBD (Cycle 1)
(Page 4 of 4)

DATE:	
Have Hypersensitivity Reaction Tray and Protocol Available	
DARATUMUMAB continued	
CYCLE 1, Days 15 and 22	
daratumumab 16 mg/kg x _____ kg = _____ mg IV in 500 mL NS (use 0.2 micron in-line filter)	
<u>Infusion rate for Days 15 and 22: Physician to determine rate of infusion</u>	
<i>If no reaction in the previous infusion or reaction is Grade 2 or less:</i>	
<input type="checkbox"/> Start at 200 mL/h. If no infusion-related reactions after 30 minutes, infuse the remainder at 450 mL/h (Rapid infusion)	
OR	
<i>If reaction in the previous infusion is Grade 3:</i>	
<input type="checkbox"/> Start at 100 mL/h. If no infusion-related reactions after 60 minutes, increase by 50 mL/h every 60 minutes to a maximum rate of 200 mL/h. Refer to protocol for modified starting rate if previous infusion reactions were experienced during infusion rate of greater than or equal to 100 mL/h. (Slow infusion)	
Vitals monitoring:	
Vital signs immediately before the start, at the end of the infusion and as needed. Observe patient for 30 minutes after infusion (observation not required after 3 treatments with no reaction).	
RETURN APPOINTMENT ORDERS	
<input type="checkbox"/> STANDARD REGIMEN: For Cycle 1, book chemo on days 1, 8, 15 and 22	
<input type="checkbox"/> ALTERNATIVE REGIMEN: For Cycle 1, book chemo on days 1, 2, 8, 15 and 22	
For Cycle 2 book chemo on days 1, 8, 15, 22	
Return in four weeks for Doctor and Cycle 2	
Laboratory: Blood work done prior to next cycle must be done less than or equal to 4 days prior to the start date	
Red Blood Cell phenotype and Group and Screen prior to cycle 1	
<u>Cycles 1 and 2:</u>	
Day 1: CBC & Diff, platelets, sodium, potassium, creatinine, calcium, ALT, bilirubin	
Day 1: <input type="checkbox"/> Serum Protein Electrophoresis and/or <input type="checkbox"/> Serum Free Light Chain Levels (SELECT APPROPRIATE)	
Day 15: CBC & Diff, platelets	
<input type="checkbox"/> Sodium, Potassium	
<input type="checkbox"/> ALT <input type="checkbox"/> bilirubin <input type="checkbox"/> Creatinine	
<input type="checkbox"/> See general orders sheet for additional requests	
<input type="checkbox"/> Other tests: _____ <input type="checkbox"/> Consults	
DOCTOR'S SIGNATURE:	SIGNATURE:
	UC: