**PROTOCOL CODE: UMYDARBD (Cycle 1)**

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

<table>
<thead>
<tr>
<th>DOCTOR’S ORDERS</th>
<th>Ht cm</th>
<th>Wt kg</th>
<th>BSA m²</th>
</tr>
</thead>
</table>

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

**DATE:**

To be given: 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 x 10⁹/L, platelets greater than or equal to 30 x 10⁹/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 x 10⁹/L, platelets greater than or equal to 80 x 10⁹/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 x 10⁹/L, platelets greater than or equal to 50 x 10⁹/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 (circle one) x BSA = _____ mg SC injection on days 1, 8, 15 and 22**

**DOCTOR'S SIGNATURE:**

**SIGNATURE:**

**UC:**
**DATE:**

<table>
<thead>
<tr>
<th><strong>DEXAMETHASONE:</strong></th>
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<tbody>
<tr>
<td>***Refer to Table 1 in protocol for steroid dosing ***</td>
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</tbody>
</table>

RN to use patient’s steroid as pre-med for daratumumab-refer to protocol. May use IV dexamethasone if PO dexamethasone not available

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

- [ ] **dexamethasone 40 mg** PO in the morning with food on days 1, 8, 15, 22
  - OR
- [ ] **dexamethasone 20 mg** PO in the morning with food on days 1, 8, 15, 22
  - OR
- [ ] **predniSONE 100 mg** PO OR methylPREDNISolone 100 mg IV (circle one) in the morning on days 1, 8, 15, 22
  - OR

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

- [ ] **dexamethasone 20 mg** PO in the morning with food on days 1 and 2, and 40mg on days 8, 15, 22
  - OR
- [ ] **dexamethasone 20 mg** PO in the morning with food on days 1, 2, 8, 15, 22
  - OR
- [ ] **predniSONE 50 mg** PO OR methylPREDNISolone 50 mg IV (circle one) in the morning on days 1 and 2, then predniSONE 100 mg PO OR methylPREDNISolone 100 mg IV (circle one) on days 8, 15, 22

**DOCTOR'S SIGNATURE:**

**SIGNATURE:**

**UC:**
**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 _________________________.

**60 minutes prior to daratumumab:**
- **dexamethasone** as ordered in dexamethasone section
- **montelukast 10 mg** PO prior to each daratumumab
- **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
- **diphenhydRAMINE 25-50 mg** PO/IV prior to each daratumumab. Repeat diphenhydramine every 4 hours x 1 dose during the infusion on day 1 of cycle 1 only, then every 4 hours when needed for allergic reaction

OR
- **loratadine 10mg** PO prior to each daratumumab, then **diphenhydRAMINE 25-50mg** PO/IV every 4 hours when needed for allergic reaction

### Standard regimen:
daratumumab full dose administered on Cycle 1 Day 1

**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

**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
DATE:  

**Have Hypersensitivity Reaction Tray and Protocol Available**

**DARATUMUMAB continued**

**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**

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

- Start at 200 mL/h. If no infusion-related reactions after 30 minutes, infuse the remainder at 450 mL/h (Rapid infusion)
- OR

*If reaction in the previous infusion is Grade 3:*

- 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.

**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)

**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:*

- Start at 200 mL/h. If no infusion-related reactions after 30 minutes, infuse the remainder at 450 mL/h (Rapid infusion)
- OR

*If reaction in the previous infusion is Grade 3:*

- 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).

**DOCTOR'S SIGNATURE:***

**SIGNATURE:***

**UC:**
<table>
<thead>
<tr>
<th><strong>DATE:</strong></th>
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<tbody>
<tr>
<td><strong>RETURN APPOINTMENT ORDERS</strong></td>
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<tr>
<td>☐ STANDARD REGIMEN: For Cycle 1, book chemo on days 1, 8, 15 and 22</td>
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<tr>
<td>☐ ALTERNATIVE REGIMEN: For Cycle 1, book chemo on days 1, 2, 8, 15 and 22</td>
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<tr>
<td>For Cycle 2 book chemo on days 1, 8, 15, 22</td>
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<tr>
<td>Return in <strong>four</strong> weeks for Doctor and Cycle 2</td>
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<tr>
<td><strong>Laboratory:</strong> Blood work done prior to next cycle must be done less than or equal to 4 days prior to the start date</td>
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<tr>
<td>Red Blood Cell phenotype and Group and Screen prior to cycle 1</td>
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<td><strong>Cycles 1-2:</strong></td>
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<tr>
<td><strong>Day 1:</strong> CBC &amp; Diff, platelets, sodium, potassium, creatinine, calcium, ALT, bilirubin</td>
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<tr>
<td><strong>Day 1:</strong> Serum Protein Electrophoresis <strong>and/or</strong> Serum Free Light Chain Levels (CIRCLE APPROPRIATE)</td>
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<td><strong>Day 15:</strong> CBC &amp; Diff, platelets</td>
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<tr>
<td>☐ Sodium, Potassium</td>
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<td>☐ ALT</td>
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<td>☐ bilirubin</td>
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<td>☐ Creatinine</td>
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<tr>
<td>☐ See general orders sheet for additional requests</td>
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<tr>
<td>☐ Other tests:</td>
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<td>☐ Consults</td>
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