PROTOCOL CODE: UMYDARBD (Cycle 2+)

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

**DOCTOR’S ORDERS**

<table>
<thead>
<tr>
<th>Ht________ cm</th>
<th>Wt________ kg</th>
<th>BSA________ m$^2$</th>
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</thead>
</table>

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

**DATE:**

To be given: __________________________

Cycle #: __________________________

Date of Previous Cycle: __________________________

****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 day 15) 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 $1.5 \times$ 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 $10 \text{ mL/min}$
  - Proceed with daratumumab day 1 dose as written, if within 96 hours (or within 48 hours for day 15) 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 – Cycle 2 onwards**
  
  cyclophosphamide $300 \text{ mg/m}^2/\text{day} \times \text{BSA} \times (\_\_\_\_\_\%) = \_\_\_\_\_\_\text{mg PO weekly}$ on days 1, 8, 15 of a 28 day cycle (maximum dose 500 mg and round to nearest 25 mg)

- **BORTEZOMIB – Cycles 2-8**
  
  - 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 $1.3 \text{ mg/m}^2$ or $1 \text{ mg/m}^2$ or $0.7 \text{ mg/m}^2$ (circle one) $\times$ BSA = ________ mg SC injection on days 1, 8, 15 and 22

**DOCTOR’S SIGNATURE:**

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**UC:**
# Protocol Code: UMYDARBD (Cycle 2+)

**DATE:**

**DEXAMETHASONE:** ***Refer to Table 1 in protocol for steroid dosing***

RN to use patient’s steroid as pre-med for daratumumab—refer to protocol.

May use IV dexamethasone if PO dexamethasone not available.

### Cycle 2

- **40 mg** weekly group – dexamethasone 20 mg PO in the morning on days 1, 2, 8, 9, 15, 16, 22, 23 **OR**
- **20 mg** weekly group – dexamethasone 20 mg PO in the morning on days 1, 8, 15, 22 and 8 mg PO on days 2, 9, 16, 23 **OR**
- ______ mg weekly group - dexamethasone 20 mg PO in the morning on day 1, 8, 15, 22 and 8 mg PO on days 2, 9, 16, 23 **OR**
- **Prednisone 50 mg** PO or methylprednisolone 50 mg IV (circle one) in the morning on days 1, 8, 15, 22 and prednisone 50 mg PO on days 2, 9, 16, 23
- No therapeutic steroid group – dexamethasone 20 mg PO in the morning with food on days 1, 8, 15, 22, and 8 mg on days 2, 9, 16, 23

### Cycles 3 to 4

- **40 mg** weekly group – dexamethasone 20 mg PO in the morning on days 1, 2, 15, 16 and 40 mg PO on days 8, 22 **OR**
- **20 mg** weekly group – dexamethasone 20 mg PO in the morning on days 1, 8, 15, 22 and 8 mg PO on days 2, 16 **OR**
- ______ mg weekly group - dexamethasone 20 mg PO in the morning on days 1, 15, and 8 mg PO on days 2, 16 **OR**
- prednisone 50 mg PO or methylprednisolone 50 mg IV (circle one) in the morning on days 1, 15, and prednisone 50 mg PO on days 2, 16, and prednisone 100 mg on days 8, 22
- No therapeutic steroid group – dexamethasone 20 mg PO in the morning with food on days 1, 15 and 8 mg on days 2, 16.

### Cycles 5 to 8

- **40 mg** weekly group – dexamethasone 20 mg PO in the morning on days 1, 2, and 40 mg on days 8, 15, 22 **OR**
- **20 mg** weekly group – dexamethasone 20 mg PO in the morning on days 1, 8, 15, 22 and 8 mg on day 2 **OR**
- ______ mg weekly group - dexamethasone 20 mg PO in the morning on day 1, 8 mg on day 2, ______ mg on days 8, 15, 22
- prednisone PO or methylprednisolone 50 mg IV (circle one) in the morning on day 1, prednisone 50 mg on day 2, and prednisone 100 mg on days 8, 15, 22
- No therapeutic steroid group – dexamethasone 20 mg PO in the morning with food on day 1, and 8 mg PO on day 2.

### Cycle 9 onward

- **40 mg** weekly group – dexamethasone 20 mg PO in the morning on days 1 and 2 **OR**
- **20 mg** weekly group – dexamethasone 20 mg PO in the morning on day 1 and 8 mg on day 2 **OR**
- ______ mg weekly group - dexamethasone 20 mg PO in the morning on day 1, 8 mg on day 2 **OR**
- prednisone 50 mg PO or methylprednisolone 50 mg IV (circle one) in the morning on day 1, prednisone 50 mg PO on day 2
- No therapeutic steroid group – dexamethasone 20 mg PO in the morning with food on day 1 and 8 mg PO on day 2.

### DOCTOR'S SIGNATURE:

### SIGNATURE:

### UC:

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BC Cancer Protocol Summary UMYDARBD

Activated: 1 Feb 2019  
Revised: 1 Nov 2019 (cycle 2+)
**DATE:**

**Have Hypersensitivity Reaction Tray and Protocol Available**

### DARATUMUMAB

**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
- acetaminophen 650 mg PO prior to each daratumumab. Repeat acetaminophen every 4 hours when needed for fever
- diphenhydramINE 25-50 mg PO/IV prior to each daratumumab. Repeat diphenhydramine every 4 hours when needed for allergic reaction

**Nursing requirements:**

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

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

### DARATUMUMAB continued

- **CYCLE 2, Days 1, 8, 15, and 22:**
  
daratatumumab $16 \text{ mg/kg} \times \underline{\text{kg}} = \underline{\text{mg}}$ IV in 500 mL NS (use 0.2 micron in-line filter)

- **CYCLE 3-4, Days 1 and 15:**
  
daratatumumab $16 \text{ mg/kg} \times \underline{\text{kg}} = \underline{\text{mg}}$ IV in 500 mL NS (use 0.2 micron in-line filter)

- **CYCLE 5 and subsequent, Day 1:**
  
daratatumumab $16 \text{ mg/kg} \times \underline{\text{kg}} = \underline{\text{mg}}$ IV in 500 mL NS (use 0.2 micron in-line filter)

**DOCTOR’S SIGNATURE:**

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**UC:**
### DATE:

<table>
<thead>
<tr>
<th>RETURN APPOINTMENT ORDERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>For Cycles 3 to 8 book chemo on days 1, 8, 15, 22</td>
</tr>
<tr>
<td>For Cycles 9 and subsequent, book chemo on day 1</td>
</tr>
<tr>
<td>☐ Return in <strong>four</strong> weeks for Doctor and Cycle 1234</td>
</tr>
<tr>
<td>☐ Last Cycle. Return in ______ week(s).</td>
</tr>
</tbody>
</table>

**Laboratory:** Blood work done prior to next cycle must be done less than or equal to 4 days prior to the start date

**Day 1:** CBC & Diff, platelets, sodium, potassium, creatinine, calcium, ALT, bilirubin

**Day 1:** Serum Protein Electrophoresis **and/or** Serum Free Light Chain Levels (CIRCLE APPROPRIATE)

**Cycles 2 to 4: Day 15:** CBC & Diff, platelets

- ☐ Sodium, Potassium
- ☐ ALT
- ☐ Creatinine
- ☐ bilirubin

- ☐ See general orders sheet for additional requests
- ☐ Other tests:
- ☐ Consults

**DOCTOR’S SIGNATURE:**

**SIGNATURE:**

**UC:**