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

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

**Patient RevAid #:____________**

<table>
<thead>
<tr>
<th><strong>DOCTOR’S ORDERS</strong></th>
<th>Ht cm</th>
<th>Wt kg</th>
<th>BSA m²</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DATE:</strong></td>
<td>To be given:</td>
<td>Cycle #: 1</td>
<td></td>
</tr>
<tr>
<td>Date of Previous Cycle:</td>
<td>______________________</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk Category:</td>
<td>[ ] Female of Childbearing Potential (FCBP) Rx valid for 7 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk Category:</td>
<td>[ ] Male or Female of non-Childbearing Potential (NCBP)</td>
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</tbody>
</table>

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

- **Delay treatment _________ week(s)**
- **CBC & Diff, Platelets** day of treatment
  - May proceed with daratumumab day 1 doses as written, if within 96 hours **ANC greater than or equal to 1 x 10⁹/L, Platelets greater than or equal to 50 x 10⁹/L**
  - May proceed with lenalidomide doses as written, if within 96 hours **ANC greater than or equal to 1 x 10⁹/L, Platelets greater than or equal to 30 x 10⁹/L, eGFR as per protocol**

**Dose modification for:**
- **Hematology: ___________________**
- **Other Toxicity: __________________________**

**Proceed with treatment based on blood work from __________________________**

**CHEMOTHERAPY:**

**LENALIDOMIDE**

- [ ] lenalidomide* ______mg PO daily, in the evening, on days 1 to 21 and off for 7 days
- [ ] lenalidomide* ______ mg PO __________________________________________

**MITTE:** *(available as 25 mg, 20mg, 15 mg, 10 mg, 5 mg and 2.5 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 assure DVT prophylaxis in place: ASA or Warfarin or LMWH (circle one)**

**DOCTOR’S SIGNATURE:**

**Signature:**

**Physician RevAid ID:**

**UC:**
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**DEXAMETHASONE:**

- **40 mg PO weekly group** – Pharmacy dispense **dexamethasone 20 mg** in the morning with food on days 1, 2, 8, 9, 15, 16, 22, 23
  (RN to use patient’s 20mg dexamethasone as pre-med for daratumumab on day 1, {and day 2 if on Alternative regimen}, days 8, 15, 22) **OR**

For patients on 20mg or less of weekly dexamethasone on Alternative regimen (split dosing), RN to use patient’s 8mg of dexamethasone on day 2 as pre-med

- **20 mg PO weekly group** – Pharmacy dispense **dexamethasone 20mg** in the morning with food on days 1, 8, 15, 22 and **dexamethasone 8mg** in the morning on days 2, 9, 16, 23
  (RN to use patient’s 20mg dexamethasone as pre-med for daratumumab on days 1, 8, 15, 22) **OR**

- **12 mg PO weekly group** – Pharmacy dispense **dexamethasone 12mg** in the morning with food on days 1, 8, 15, 22 and **dexamethasone 8mg** in the morning on days 2, 9, 16, 23
  (RN to use patient’s 12mg dexamethasone PLUS top up with 8mg dexamethasone as pre-med for daratumumab on days 1, 8, 15, 22) **OR**

- **________ mg PO weekly group**– Pharmacy dispense **dexamethasone ________ mg** in the morning on days 1, 8, 15, 22 and **dexamethasone 8mg** in the morning on days 2, 9, 16, 23
  (RN to use patient’s dexamethasone PLUS top up (to 20mg) with ________mg dexamethasone PO/IV (circle one) as pre-med for daratumumab on days 1, 8, 15, 22) **OR**

- **prednisone 50mg PO** in the morning on days 1, 2, 8, 9, 15, 16, 22 and 23
  (RN to use patient’s 50mg prednisone as pre-med for daratumumab on day 1 {and day 2 if on Alternative regimen}, days 8, 15, 22) **OR**

- **No Steroid group**– Pharmacy dispense **dexamethasone 8mg** in the morning with food on days 2, 9, 16, 23
  (RN to give 20mg dexamethasone PO/IV (circle one) pre-daratumumab on days 1, 8, 15, 22)

***Refer to table 1 in protocol and dexamethasone table in Appendix for steroid dosing***

**DARATUMUMAB**

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

**DARATUMUMAB PREMEDICATIONS:**

Patient to take own supply dispensed by pharmacy. RN/Pharmacist to confirm ____________________________.

60 minutes prior to daratumumab

1. Ensure patient has taken dexamethasone dose as ordered in dexamethasone section
2. Ensure patient has taken 10mg montelukast

- **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

**DOCTOR’S SIGNATURE:**

| SIGNATURE: |
| UC: |
**DATE:**

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

**DARATUMUMAB continued:**

**Nursing requirements for D1, (D2 if Alternative regimen):**
Start at 50mL/hour. If no infusion-related reactions after 60 minutes, increase by 50mL/hour every 60 minutes to a maximum rate of 200mL/hour.
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.

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.

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

- **CYCLE 1, Day 1:**
  - daratumumab (First dose) 16mg/kg x _________ kg = _______ mg
  - IV in 1000mL 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 8mg/kg x _________ kg = _______ mg
  - IV in 500mL NS (use 0.2 micron in-line filter)

**Nursing requirements for D8:**
Start at 50mL/hour. If no infusion-related reactions after 60 minutes, increase by 50mL/hour every 60 minutes to a maximum rate of 200mL/hour.

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

- **CYCLE 1, Day 8**
  - daratumumab 16mg/kg x _________ kg = _______ mg
  - IV in 500mL NS (use 0.2 micron in-line filter)

**DOCTOR’S SIGNATURE:**

**SIGNATURE:**

**UC:**
DATE:  

**Have Hypersensitivity Reaction Tray and Protocol Available**

**DARATUMUMAB continued**

**Nursing requirements for D15 and D22:**

Start at 100mL/h. If no infusion-related reactions after 60 minutes, increase by 50mL/hour every 60 minutes to a maximum rate of 200mL/hour. Refer to protocol for modified starting rate if previous infusion reactions were experienced during infusion rate of greater than or equal to 100mL/h.

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

**CYCLE 1, Days 15 and 22:**

daratumab 16mg/kg x _________ kg = __________mg

IV in 500mL NS (use 0.2 micron in-line filter)

**RETURN APPOINTMENT ORDERS**

☐ STANDARD REGIMEN: For Cycle 1, book chemo on days 1, 8, 15 and 22

☐ ALTERNATIVE REGIMEN: For Cycle 1, book chemo on days 1, 2, 8, 15 and 22

Ensure patient is aware to take dexamethasone, montelukast, acetaminophen and diphenhydramine 60 minutes prior to infusion

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

**Cycles 1-2:**

Cycling & Diff, Platelets, Creatinine, Calcium every two weeks

**Cycles 1-2:**

**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)

**Day 8, 15, 22:** CBC & Diff, platelets

☐ Sodium, Potassium ☐ ALT ☐ Creatinine ☐ Bilirubin

TSH Every three months

☐ Pregnancy blood test for FCBP, every 4 weeks, less than or equal to 7 days prior to the next cycle

☐ See general orders sheet for additional requests

☐ Other tests: ☐ Consults:

**DOCTOR'S SIGNATURE:**

**SIGNATURE:**

**UC:**