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>DOCTOR’S ORDERS</th>
<th>Ht__________cm</th>
<th>Wt__________kg</th>
<th>BSA__________m²</th>
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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
- □ 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
  - May proceed with daratumumab day 1 doses as written, if within 96 hours (or within 48h for days 8, 15, 22) 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, 20 mg, 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)

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<tr>
<th>DOCTOR’S SIGNATURE:</th>
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<tr>
<td>Physician RevAid ID:</td>
<td>UC:</td>
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</tbody>
</table>

Pharmacy Use for Lenalidomide:

- RevAid confirmation number:
- Lenalidomide lot number:
- Pharmacist counsel (initial):

BC Cancer Protocol Summary UMYDARLD
Activated: 1 Feb 2019 Revised: 1 Nov 2019 (cycle 1 ppo)
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

☐ For patients on 40 mg of weekly therapeutic dexamethasone:
dexamethasone 20 mg PO in the morning with food on days 1, 2, 8, 9, 15, 16, 22, 23

OR

☐ For patients on 20 mg or less of weekly therapeutic dexamethasone
dexamethasone 20 mg PO in the morning with food on days 1, 8, 15, 22 and dexamethasone 8 mg in the morning 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 in the morning on days 2, 9, 16, 23

OR

☐ No therapeutic steroid group—dexamethasone 20 mg PO in the morning with food on days 1, 8, 15, 22 and dexamethasone 8 mg in the morning with food on days 2, 9, 16, 23

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. 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 × 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 × 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 50 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.
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) 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)

Nursing requirements for D8:
Start at 50 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.

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 16 mg/kg x _________ kg = __________mg IV in 500 mL NS (use 0.2 micron in-line filter)

OR

☐ For patients on Standard regimen AND experienced infusion reaction on day 1:
daratumumab 16 mg/kg x _________ kg = __________mg IV in 1000 mL NS (use 0.2 micron in-line filter). Refer to protocol for rate.

DOCTOR'S SIGNATURE:  

SIGNATURE:  

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

**DATE:**

**DARATUMUMAB continued**

**Nursing requirements for D15 and D22:**

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 and at the end of the infusion. Observe patient for 30 minutes after infusion.

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

\[
\text{daratumumab 16 mg/kg} \times \underline{\text{kg}} = \underline{\text{mg}}
\]

IV in 500 mL 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
  
  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:**

CBC & 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 7-14 days and 24 h prior to cycle 1 and every week for 4 weeks during cycle 1
- Pregnancy blood test for FCBP less than or equal to 7 days prior to cycle 2
- See general orders sheet for additional requests
- Other tests:

**DOCTOR'S SIGNATURE:**

**SIGNATURE:**

**UC:**