

**PROTOCOL CODE: MYDARLDF (IV Cycle 1)**

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Patient RevAid # \_\_\_\_\_

|  |                     |                   |                   |   |
|--|---------------------|-------------------|-------------------|---|
| <b>DOCTOR'S ORDERS</b>   |                     | Ht _____ cm       | Wt _____ kg       | BSA _____ m <sup>2</sup>  |
| REMINDER: Please ensure drug allergies and previous bleomycin are documented on the Allergy & Alert Form   |                     |                   |                   |   |
| <b>DATE:</b>   | <b>To be given:</b> | <b>Cycle #: 1</b> |                   |   |
| Date of Previous Cycle: _____  |                     |                   |                   |   |
| Risk Category: <input type="checkbox"/> Female of Childbearing Potential (FCBP) Rx valid for 7 days  |                     |                   |                   |   |
| Risk Category: <input type="checkbox"/> Male or Female of non-Childbearing Potential (NCBP)  |                     |                   |                   |   |
| ****Ensure Red Blood Cell Phenotype and Group and Screen for all patients prior to Cycle 1****   |                     |                   |                   |   |
| <input type="checkbox"/> Delay treatment _____ week(s)<br><input type="checkbox"/> CBC & Diff, Platelets day of treatment <ul style="list-style-type: none"> <li>• May proceed with daratumumab Day 1 doses as written, if within 96 hours (or within 48 h for Days 8, 15, 22) <b>ANC greater than or equal to 1.0 x 10<sup>9</sup>/L, Platelets greater than or equal to 50 x 10<sup>9</sup>/L</b></li> <li>• May proceed with lenalidomide doses as written, if within 96 hours <b>ANC greater than or equal to 1.0 x 10<sup>9</sup>/L, Platelets greater than or equal to 30 x 10<sup>9</sup>/L, eGFR as per protocol</b></li> </ul>  |                     |                   |                   |   |
| Dose modification for: <input type="checkbox"/> Hematology: _____ <input type="checkbox"/> Other Toxicity: _____   |                     |                   |                   |   |
| Proceed with treatment based on blood work from _____  |                     |                   |                   |   |
| <b>CHEMOTHERAPY:</b><br><b>LENALIDOMIDE</b><br><input type="checkbox"/> lenalidomide* _____ mg PO daily, in the evening, on days 1 to 21 and off for 7 days<br><input type="checkbox"/> lenalidomide* _____ mg PO _____<br>(*available as 25 mg, 20 mg, 15 mg, 10 mg, 5 mg and 2.5 mg capsules)<br>*Note: Use one capsule strength for the total dose; there are cost implications as costing is per capsule and not weight based<br><br>Mitte:<br><input type="checkbox"/> FCBP dispense 21 capsules (1 cycle)<br><input type="checkbox"/> For Male and Female NCBP: Mitte: 21 capsules (1 cycle).<br><br><b>Physician to assure DVT prophylaxis in place: ASA, Warfarin, low molecular weight heparin or direct oral anticoagulant or none</b> |                     |                   |                   | <u>Pharmacy Use for Lenalidomide:</u><br><br>RevAid confirmation number: _____<br><br>Lenalidomide lot number: _____<br><br>Pharmacist counsel (initial): _____ |
| <b>DOCTOR'S SIGNATURE:</b>   |                     |                   | <b>SIGNATURE:</b> |   |
| <b>Physician Revaid ID:</b>  |                     |                   | <b>UC:</b>        |   |

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**DATE:**

**STERIOD:** 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 daratumumb on days 8, 15, 22

OR

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

OR

predniSONE 50 mg PO before daratumumab on days 1 and 2, and predniSONE 100 mg before daratumumb 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 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 650 mg PO every 4 hours x 1 dose during infusion on day 1 of cycle 1 only, then every 4 hours when needed

Select one of the following:

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

OR

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

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**DATE:**

**\*\*Have Hypersensitivity Reaction Tray and Protocol Available\*\***

**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, pruritus, 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

**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.

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| <b>DATE:</b>  |                   |
| <b>**Have Hypersensitivity Reaction Tray and Protocol Available**</b>   |                   |
| <b>CYCLE 1, Days 15 and 22:</b>   |                   |
| daratumumab 16 mg/kg x _____ kg = _____ mg IV in 500 mL NS (use 0.2 micron in-line filter)  |                   |
| <b><u>Infusion rate for Days 15 and 22: Physician to determine rate of infusion</u></b>   |                   |
| <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 after 30 minutes, infuse the remainder at 450 mL/h (Rapid infusion)  |                   |
| <b>OR</b>   |                   |
| <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) |                   |
| <b>Vitals monitoring:</b> Vital signs immediately before the start, at the end of the infusion and as needed. Observe patient for 30 minutes after infusion. (Vitals and observation post-infusion not required after 3 treatments with no reaction).   |                   |
| <b>RETURN APPOINTMENT ORDERS</b>  |                   |
| <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 <b>four</b> weeks for Doctor and Cycle 2  |                   |
| <b>Laboratory:</b> 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  |                   |
| <b><u>Cycles 1 to 2:</u></b>  |                   |
| <b>Day 1:</b> CBC & Diff, platelets, sodium, potassium, creatinine, calcium, ALT, bilirubin, serum protein electrophoresis, serum free light chain levels   |                   |
| <b>Day 8, 15, 22:</b> CBC & Diff, platelets   |                   |
| <input type="checkbox"/> <b>CBC &amp; Diff, platelets, creatinine, calcium</b> every two weeks  |                   |
| TSH every three months  |                   |
| If clinically indicated: <input type="checkbox"/> immunoglobulin panel <input type="checkbox"/> urine protein electrophoresis   |                   |
| <input type="checkbox"/> sodium, potassium <input type="checkbox"/> ALT <input type="checkbox"/> bilirubin <input type="checkbox"/> creatinine  |                   |
| <input type="checkbox"/> Quantitative $\beta$ -hCG blood test for FCBP 7-14 days and 24 h prior to cycle 1 and every week for 4 weeks during cycle 1  |                   |
| <input type="checkbox"/> Quantitative $\beta$ -hCG blood test for FCBP less than or equal to 7 days prior to cycle 2  |                   |
| <input type="checkbox"/> See general orders sheet for additional requests   |                   |
| <input type="checkbox"/> Other tests:   |                   |
| <input type="checkbox"/> Consults:  |                   |
| <b>DOCTOR'S SIGNATURE:</b>  | <b>SIGNATURE:</b> |
|   | <b>UC:</b>        |