

For Health Professionals Who Care For Cancer Patients

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ADDENDUM

DARATUMUMAB PROTOCOL/PPPO CHANGES

The following revised **Daratumumab-containing Chemotherapy Protocols and PPPOs** were announced in the [July 2019](#) issue of the Systemic Therapy Update. The current addendum is intended to provide clinicians specific details about such revisions.

CODE	Protocol Title
UMYDARBD	Treatment of Relapsed and Refractory Multiple Myeloma with Daratumumab in Combination with Bortezomib and Dexamethasone with or without Cyclophosphamide
UMYDARLD	Treatment of Relapsed and Refractory Multiple Myeloma with Daratumumab in Combination with Lenalidomide and Dexamethasone

Key changes to the above Protocols and/or PPPOs are summarized below:

1. Clarified dexamethasone dosing:

- Background:
 - Dexamethasone is used **BOTH** as a therapeutic agent in the overall treatment of multiple myeloma **AND** as a premedication to prevent daratumumab-associated infusion reactions. The standard therapeutic dexamethasone dose is 40 mg per week (20 mg prior to daratumumab and 20 mg the next day). This dose is sufficient to prevent daratumumab-associated infusion reactions; hence, no dexamethasone top-up doses (for premedication purposes) are required.
- Protocol updates:
 - *Premedications* clarified – When the weekly therapeutic dexamethasone dose is 20 mg or less, patients should be given 20 mg prior to daratumumab and 8 mg the next day to reduce the risk of infusion-related reactions on days that daratumumab is given. Hence, top-ups may be needed.
Note: On days when the patient is not receiving daratumumab (e.g. cycle 5 – days 8, 15 and 22), the weekly therapeutic dexamethasone dose should be taken on a single day and no additional top-ups are needed.
 - *New Appendix* – A dexamethasone dosing table was created to guide clinicians on what dexamethasone doses should be given pre-daratumumab and the next day.

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2. Divided original PPPO into two separate PPPOs for ease of use:
 - Cycle 1
 - Cycle 2 and beyond
3. Reduced post-infusion observation period to 30 minutes for ALL cycles:
 - Previously, the observation period in cycle 1 (days 1 and 8) was 2 hours

A **Daratumumab Working Group** is currently reviewing the operational processes on how to best supply dexamethasone top-up doses to patients. Please stay tuned for further changes to the protocols and PPPOs to improve the clarity of these documents.

UPDATED DARATUMUMAB OBSERVATION PERIOD: ST POLICY III-60 APPENDIX

The reduced daratumumab post-infusion observation period noted above has now been updated in the **Systemic Therapy Drug Reaction Management Policy (III-60) [Appendix](#)** under Table 1 (Duration of physician coverage per parenteral drugs).

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