Regimen Monograph

A - Regimen Name

BORTDEXALENA+DARA(SC) Regimen

Bortezomib-Dexamethasone-Lenalidomide-Daratumumab (subcut)

LENA+DARA(MNT-SC) Regimen

Lenalidomide-Daratumumab (subcut) (Maintenance)

Disease Site

Hematologic
Multiple Myeloma

Intent

Palliative

Regimen Category

Evidence-informed :

Regimen is considered appropriate as part of the standard care of patients; meaningfully improves outcomes (survival, quality of life), tolerability or costs compared to alternatives (recommended by the Disease Site Team and national consensus body e.g. pan-Canadian Oncology Drug Review, pCODR). Recommendation is based on an appropriately conducted phase III clinical trial relevant to the Canadian context OR (where phase III trials are not feasible) an appropriately sized phase II trial. Regimens where one or more drugs are not approved by Health Canada for any indication will be identified under Rationale and Use.

This **Regimen Abstract** is an **abbreviated** version of a Regimen Monograph and contains only top level information on usage, dosing, schedule, cycle length and special notes (if available). Information in regimen abstracts is accurate to the extent of the ST-QBP regimen master listings, and has not undergone the full review process of a regimen monograph. Full regimen monographs will be published for each ST-QBP regimen as they are developed.

Rationale and

Treatment of newly diagnosed multiple myeloma in transplant-eligible patients

Uses

Supplementary Public Funding	**bortezomib** New Drug Funding Program (Bortezomib - Previously Untreated - Multiple Myeloma Pre-Stem Cell Transplant) (NDFP Website) (Funded for induction only) **dexamethasone** ODB - General Benefit (dexamethasone) (ODB Formulary)

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B - Drug Regimen

Daratumumab IV and subcutaneous formulations are **not interchangeable**. The dosing and administration of these products are different.

Cycles 1 to 2 (Pre-transplant induction):

daratumumab (subcut)	1800 mg	Subcut	Days 1, 8, 15, 22
(This drug is not currently publicly funded for this regimen and intent)			
bortezomib*	1.5 mg /m²	IV / Subcut	Days 1, 8, 15, 22
lenalidomide	25 mg	PO	Days 1 to 21
(This drug is not currently publicly funded for this regimen and intent)			
dexamethasone[1]	40 mg	IV / PO	Days 1, 8, 15, 22

Cycles 3 to 4 (Pre-transplant induction):

daratumumab (subcut)	1800 mg	Subcut	Days 1 and 15
(This drug is not currently publicly funded for this regimen and intent)			
bortezomib*	1.5 mg /m²	IV / Subcut	Days 1, 8, 15, 22
lenalidomide	25 mg	PO	Days 1 to 21
(This drug is not currently publicly funded for this regimen and intent)			
dexamethasone[1]	40 mg	IV / PO	Days 1, 8, 15, 22

Cycles 5 and 6 (Post-transplant consolidation):

daratumumab (subcut)	1800 mg	Subcut	Days 1 and 15
(This drug is not currently publicly funded for this regimen and intent)			
bortezomib*	1.5 mg /m²	IV / Subcut	Days 1, 8, 15, 22
(This drug is not currently publicly funded for this regimen and intent)			
lenalidomide	25 mg	PO	Days 1 to 21
(This drug is not currently publicly funded for this regimen and intent)			
dexamethasone[1]	40 mg	IV / PO	Days 1, 8, 15, 22

Then LENA+DARA(MNT-SC):

daratumumab (subcut)	1800 mg	Subcut	Day 1
(This drug is not currently publicly funded for this regimen and intent)			
lenalidomide[2]	10 mg	PO	Days 1 to 21
(This drug is not currently publicly funded for this regimen and intent)			

Lenalidomide may only be prescribed and dispensed by physicians and pharmacists registered with a controlled distribution program. Patients must also be registered and meet all conditions of the program.

* The bortezomib dose was 1.3 mg/m^2 subcut on Days 1, 4, 8, 11 during cycles 1 to 6, in the PERSEUS trial.

[1] In elderly patients, the dexamethasone dose should be reduced (i.e. to 20 mg once weekly).

[2] May increase lenalidomide to 15 mg daily on days 1-21 after 3 maintenance cycles

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C - Cycle Frequency

REPEAT EVERY 28 DAYS

For 4 induction cycles before transplant and 2 consolidation cycles post-transplant, followed by lenalidomide and daratumumab maintenance (LENA+DARA(MNT-SC)), until disease progression or unacceptable toxicity

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D - Premedication and Supportive Measures

Antiemetic Regimen: Low
No routine prophylaxis for lenalidomide

- Also refer to CCO Antiemetic Recommendations.

Screen for hepatitis B virus in all cancer patients starting systemic treatment. Refer to the hepatitis B virus screening and management guideline.

Pre-medications for daratumumab (subcut) (prophylaxis for administration-related reactions (ARRs)):

To be given at least 1 hour prior to each dose:

- Dexamethasone 20 mg IV/PO†
- Oral antipyretic (e.g., acetaminophen 650-1000 mg)
- H1-receptor antagonist IV/PO (e.g., diphenhydramine 25-50 mg or equivalent)
- Montelukast 10 mg PO‡

†Dexamethasone on the day of injection may be given as part of pre-/post-medications for daratumumab; 20 mg IV/PO on the day of daratumumab injection and 20 mg PO on the day after injection. For patients receiving reduced dose dexamethasone 20 mg weekly, the entire 20 mg dose has been given prior to the daratumumab injection in some clinical trials.

‡Montelukast 10 mg was optional on Cycle 1 Day 1 during clinical trials of daratumumab (subcut). The addition of montelukast given prior to the first daratumumab IV infusion numerically reduced the incidence of respiratory IRs in the study by Nooka et al.

Post-injection medications for daratumumab (subcut) (prevention of delayed ARRs):

- Dexamethasone 20 mg PO for 1 day post-injection[¶,§]
- Consider bronchodilators (e.g., short and long acting) and inhaled corticosteroids (for patients with a history of COPD)[‖,#]

[¶]Dexamethasone on the day of injection may be given as part of pre-/post-medications for daratumumab; 20 mg IV/PO on the day of daratumumab infusion and 20 mg PO on the day after injection. For patients receiving reduced dose dexamethasone 20 mg weekly, the entire 20 mg dose has been given prior to the daratumumab injection in some clinical trials.

[§]This may be discontinued after the 3rd injection if no major systemic ARRs occurred.

[‖]Consider adding an H1-receptor antagonist if the patient is at higher risk of respiratory complications.

[#]These may be discontinued after the 4th injection if no major ARRs occurred.

Other Supportive Care:

- Daratumumab can interfere with cross-matching for blood transfusions; type and screen and RBC genotyping tests should be done before starting this drug.
- Antiviral prophylaxis for herpes zoster is recommended.
- Patients at risk of tumour lysis syndrome should have appropriate prophylaxis and be monitored closely.
- For lenalidomide, prophylaxis for venous thromboembolism is recommended in patients at risk.
- Careful consideration and monitoring must be taken with erythropoietin stimulating agents (ESAs), since the concomitant use of ESAs with lenalidomide may potentiate the risk of thrombosis. RBC or platelet transfusions with lenalidomide dose reductions/interruptions may be appropriate in severe / symptomatic anemia or thrombocytopenia.
- Optimal control of thyroid function is recommended prior to starting lenalidomide treatment.

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J - Administrative Information

Lenalidomide, Dexamethasone: Outpatient prescription for home administration

Approximate Patient Visit
BORTDEXALENA+DARA(SC) 5 hours
LENA+DARA(MNT-SC) 1.5 hours

Pharmacy Workload **(average time per visit)**
BORTDEXALENA+DARA(SC) 6.369 minutes

Nursing Workload **(average time per visit)**
BORTDEXALENA+DARA(SC) 7.50 minutes

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K - References

Bortezomib drug monograph. Ontario Health (Cancer Care Ontario).

Daratumumab (subcut) drug monograph. Ontario Health (Cancer Care Ontario).

Lenalidomide drug monograph. Ontario Health (Cancer Care Ontario).

Sonneveld P, Dimopoulos MA, Boccadoro M, et al. Daratumumab, Bortezomib, Lenalidomide, and Dexamethasone for Multiple Myeloma. N Engl J Med 2024 Jan 25;390(4):301-13. doi: 10.1056/NEJMoa2312054.

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M - Disclaimer

Regimen Abstracts

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Regimen Monographs

Refer to the New Drug Funding Program or Ontario Public Drug Programs websites for the most up-to-date public funding information.

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