Regimen Monograph

A - Regimen Name

BORTDEXALENA+DARA Regimen

Bortezomib-Dexamethasone-Lenalidomide-Daratumumab

LENA+DARA(MNT) Regimen

Lenalidomide-Daratumumab (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)
	dexamethasone ODB - General Benefit (dexamethasone) (ODB Formulary)

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B - Drug Regimen

Cycles 1 to 4 (Pre-transplant induction):

daratumumab	16 mg /kg	IV	Days 1, 8, 15
(This drug is not currently publicly funded for this regimen and intent)			
bortezomib	1.3 mg /m²	IV / Subcut	Days 1, 4, 8, 11
lenalidomide	25 mg	PO	Days 1 to 14
(This drug is not currently publicly funded for this regimen and intent)			
dexamethasone[1]	20 mg	IV / PO	Days 1, 2, 8, 9, 15, and 16

Cycles 5 to 6 (Post-transplant consolidation):

daratumumab	16 mg /kg	IV	Day 1
(This drug is not currently publicly funded for this regimen and intent)			
bortezomib	1.3 mg /m²	IV / Subcut	Days 1, 4, 8, 11
lenalidomide	25 mg	PO	Days 1 to 14
(This drug is not currently publicly funded for this regimen and intent)			
dexamethasone[1]	20 mg	IV / PO	Days 1, 2, 8, 9, 15, 16

Then,

LENA+DARA(MNT):

daratumumab	16 mg /kg	IV	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.

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

[2] May increase lenalidomide to 15 mg after 3 cycles

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C - Cycle Frequency

REPEAT EVERY 28 DAYS

For 4 induction cycles before transplant and 2 consolidation cycles post-transplant

LENA+DARA(MNT): Repeat every 28 days until disease progression or unacceptable toxicity, or up to 2 years total

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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.

Daratumumab pre-medications (prophylaxis for infusion reaction):

To be given at least 1 hour prior to daratumumab infusion:

- 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)
- Famotidine 20 mg IV (or equivalent)
- Montelukast 10 mg PO**

*Administer IV prior to the first infusion; Oral administration may be considered prior to subsequent infusions. Dexamethasone on the day of infusion 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 infusion. For patients receiving reduced dose dexamethasone 20 mg weekly, the entire 20 mg dose has been given prior to the daratumumab infusion in some clinical trials.

**The addition of montelukast given prior to the first infusion numerically reduced the incidence of respiratory IRs in the study by Nooka et al.

Post-daratumumab infusion medications (prevention of delayed reactions):

- Dexamethasone 20 mg PO on the day after daratumumab infusion*
- Consider bronchodilators (e.g. short and long acting) and inhaled corticosteroids if chronic obstructive pulmonary disorder&****

*Dexamethasone on the day of infusion 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 infusion. For patients receiving reduced dose dexamethasone 20 mg weekly, the entire 20 mg dose has been given prior to the daratumumab infusion in some clinical trials.

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

***These may be discontinued after the 4th infusion if no major IRs occurred.

Other Supportive Care:

- HBV screening should be performed in all patients prior to starting daratumumab.
- 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 (e.g. low dose aspirin 81-100 mg PO daily or enoxaparin 40 mg SC daily).
- 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.
- Consider GCSF as secondary prophylaxis.
- 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 Bortezomib: 0.5 hours; Daratumumab: 2.5 to 7.5 hours (depending on duration of infusion)

Pharmacy Workload **(average time per visit)**
BORTDEXALENA+DARA 16.369 minutes

Nursing Workload **(average time per visit)**
BORTDEXALENA+DARA 27.5 minutes

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K - References

Bortezomib, daratumumab and lenalidomide drug monographs. Ontario Health (Cancer Care Ontario).

Voorhees PM, Kaufman JL, Laubach J, et al. Daratumumab, lenalidomide, bortezomib, and dexamethasone for transplant-eligible newly diagnosed multiple myeloma: the GRIFFIN trial. Blood 2020 Aug 20;136(8):936-45.

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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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