Regimen Monograph

Regimen Name | Drug Regimen | Cycle Frequency | Premedication and Supportive Measures | Administrative Information |
References | Other Notes | Disclaimer

A - Regimen Name

BORTDEXALENA(LD) Regimen

Bortezomib-Dexamethasone-Lenalidomide (RVD-Lite) (For transplant-eligible patients)

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 Uses

For treatment of **transplant eligible** patients with previously untreated multiple myeloma. Consider use in patients who cannot tolerate the BORTDEXALENA regimen.

Supplementary Public Funding

bortezomib

New Drug Funding Program (Bortezomib - In Combination with Lenalidomide and Dexamethasone for Previously Untreated Multiple Myeloma Pre-SCT) (NDFP Website)

lenalidomide

ODB Limited Use (lenalidomide - Induction therapy for transplant eligible, newly diagnosed multiple myeloma, according to clinical criteria) (ODB Formulary)

dexamethasone

ODB - General Benefit (dexamethasone) (ODB Formulary)

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B - Drug Regimen			
<u>bortezomib</u>	1.3 mg /m²	IV / Subcut	Days 1, 8, 15, 22
<u>lenalidomide</u> ¹	15 mg	PO	Days 1 to 21
dexamethasone	20 mg	PO	Days 1, 2, 8, 9, 15, 16, 22, 23

¹ 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.

Alternative dosing schedules were described by Okazuka et al and Mookerjee et al. (See References section.)

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C - Cycle Frequency

REPEAT EVERY 28 DAYS

Give up to 4 cycles and assess for response and suitability for transplant.

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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 <u>hepatitis B virus screening and management</u> guideline.

Other Supportive Care:

- Antiviral prophylaxis for herpes zoster is recommended.
- Patients at risk of tumour lysis syndrome should have appropriate prophylaxis and be monitored closely.
- 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.
- Consider GCSF as secondary prophylaxis.
- Optimal control of thyroid function is recommended prior to starting lenalidomide treatment.

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J - Administrative Information

Outpatient prescription for home administration (lenalidomide & dexamethasone)

Bortezomib:

Approximate Patient Visit 0.5 hour

Pharmacy Workload (average time per visit) 16.369 minutes

Nursing Workload (average time per visit) 27.5 minutes

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K - References

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

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

Mookerjee A, Gupta R, Jasrotia S, et al., Bortezomib, lenalidomide and low-dose dexamethasone (VRD) versus lenalidomide and low-dose dexamethasone (Ld) for newly-diagnosed multiple myeloma-a randomized phase III study. Blood 2017;130:906.

O'Donnell EK, Laubach JP, MD, Yee AJ, et al. Updated results of a phase 2 study of modified lenalidomide, bortezomib, and dexamethasone (RVd-lite) in transplant-ineligible multiple myeloma. Blood 2019;134 (Supplement 1):3178.

O'Donnell EK, Laubach JP, Yee AJ, et al. A phase 2 study of modified lenalidomide, bortezomib and dexamethasone in transplant-ineligible multiple myeloma. Br J Haematol 2018 Jul;182(2):222-30.

Okazuka K, Ishida T, Nashimoto J, et al. The efficacy and safety of modified bortezomiblenalidomide-dexamethasone in transplant-eligible patients with newly diagnosed multiple myeloma. Eur J Haematol 2020 Feb;104(2):110-15.

PEBC Advice Documents or Guidelines

Treatment of Multiple Myeloma: ASCO and CCO Joint Clinical Practice Guideline

December 2023 new ST-QBP regimen

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M - Disclaimer

Regimen Abstracts

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Regimen Monographs

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

The information set out in the drug monographs, regimen monographs, appendices and symptom management information (for health professionals) contained in the Drug Formulary (the "Formulary") is intended for healthcare providers and is to be used for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or adverse effects of a particular drug, nor should it be construed to indicate that use of a particular drug is safe, appropriate or effective for a given condition. The information in the Formulary is not intended to constitute or be a substitute for medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.

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