#### Regimen Monograph

Regimen Name | Drug Regimen | Cycle Frequency | Premedication and Supportive Measures | Dose Modifications | Adverse |
Effects | Interactions | Drug Administration and Special Precautions | Recommended Clinical Monitoring | Administrative |
Information | References | Other Notes | Disclaimer

#### A - Regimen Name

# **BORTDEXALENA+ISAT** Regimen

Bortezomib-Dexamethasone-Lenalidomide-Isatuximab

# DEXALENA+ISAT(MNT) Regimen

Dexamethasone-Lenalidomide-Isatuximab (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-ineligible

**Uses** patients

Supplementary Public Funding

**bortezomib** 

New Drug Funding Program (Bortezomib - Previously Untreated - Multiple

Myeloma) (NDFP Website) (Funded for induction only)

dexamethasone

ODB - General Benefit (dexamethasone) (ODB Formulary)

#### back to top

## **B** - Drug Regimen

# Induction Cycle 1 (BORTDEXALENA+ISAT):

<u>isatuximab</u> 10 mg /kg IV Days 1, 8, 15, 22, 29

(This drug is not currently publicly funded for this regimen and intent)

bortezomib 1.3 to 1.5 mg /m² IV / Subcut Days 1, 8, 15, 22, 29

**dexamethasone**<sup>1</sup> 20 mg IV / PO Days 1, 2, 8, 9, 15,

16, 22, 23, 29, 30 lenalidomide 25 mg PO Days 1-14,and 22-35

(This drug is not currently publicly funded for this regimen and intent)

#### Induction Cycles 2 to 4 (BORTDEXALENA+ISAT):

<u>isatuximab</u> 10 mg /kg IV Day 1, 15, 29

(This drug is not currently publicly funded for this regimen and intent)

bortezomib 1.3 to 1.5 mg/m<sup>2</sup> IV / Subcut Days 1, 8, 15, 22, 29

**dexamethasone**<sup>1</sup> 20 mg IV / PO Days 1, 2, 8, 9, 15,

16, 22, 23, 29, 30

<u>lenalidomide</u> 25 mg PO Days 1-14,and 22-35

(This drug is not currently publicly funded for this regimen and intent)

Continuation Cycles 5 to 17 (DEXALENA+ISAT(MNT)):

<u>isatuximab</u> 10 mg /kg IV Days 1, 15

(This drug is not currently publicly funded for this regimen and intent)

dexamethasone<sup>1</sup> 20 mg IV / PO Days 1, 8, 15, 22

<u>lenalidomide</u> 10 mg PO Days 1 to 21

(This drug is not currently publicly funded for this regimen and intent)

## Continuation Cycles 18 and Beyond (DEXALENA+ISAT(MNT)):

<u>isatuximab</u> 10 mg /kg Day 1

(This drug is not currently publicly funded for this regimen and intent)

dexamethasone<sup>1</sup> 20 mg IV / PO Days 1, 8, 15, 22

<u>lenalidomide</u> 25 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.

#### back to top

#### C - Cycle Frequency

Induction: Repeat every 42 days for up to 4 cycles

Continuation: Repeat every 28 days, until disease progression or unacceptable toxicity

back to top

<sup>&</sup>lt;sup>1</sup> In elderly patients, the dexamethasone dose should be reduced (i.e. to 20 mg once weekly).

### **D** - Premedication and Supportive Measures

Antiemetic Regimen: Low

No routine prophylaxis for lenalidomide

Also refer to <u>CCO Antiemetic Recommendations</u>.

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

# Isatuximab pre-medications (prophylaxis for infusion reaction):

To be given 15-60 minutes prior to infusion:

- Dexamethasone IV/PO\*^
- Acetaminophen 650-1000 mg PO (or equivalent)
- Diphenhydramine 25-50 mg IV/PO (or equivalent)<sup>†</sup>
- H2 antagonist

\*When dexamethasone is part of isatuximab combination therapy, the treatment dose will serve as pre-medication on infusion days.

^Give dexamethasone IV on the days of isatuximab administration and PO on the other days. (based on isatuximab product monograph)

<sup>†</sup>IV preferred for at least the first 4 infusions.

#### **Other Supportive Care:**

- Isatuximab 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.
- Consider antibacterial prophylaxis during induction.
- 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.
- Optimal control of thyroid function is recommended prior to starting lenalidomide treatment.

#### back to top

#### J - Administrative Information

Lenalidomide, Dexamethasone: Outpatient prescription for home administration

Pharmacy Workload (average time per visit)
BORTDEXALENA+ISAT 16.369 minutes
Nursing Workload (average time per visit)
BORTDEXALENA+ISAT 27.5 minutes

#### back to top

#### K - References

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

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

Facon T, Dimopoulos MA, Leleu XP, et al. Isatuximab, bortezomib, lenalidomide, and dexamethasone for multiple myeloma. N Engl J Med 2024;391(17):1597-609. doi: 10.1056/NEJMoa2400712.

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

July 2025 new ST-QBP regimen

back to top

#### M - Disclaimer

#### Regimen Abstracts

A 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). It is intended for healthcare providers and is to be used for informational purposes only. It is not intended to constitute or be a substitute for medical advice, and all uses of the Regimen Abstract are subject to clinical judgment. Such information is provided on an "as-is" basis, without any representation, warranty, or condition, whether express, or implied, statutory or otherwise, as to the information's quality, accuracy, currency, completeness, or reliability, and Cancer Care Ontario disclaims all liability for the use of this information, and for any claims, actions, demands or suits that arise from such use.

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.

#### 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.

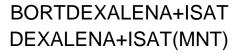
The information set out in the drug monographs, regimen monographs, appendices and symptom management information (for health professionals) contained in the Drug Formulary (the "Formulary") is intended for healthcare providers and is to be used for informational purposes only. The information is not 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.

The format and content of the drug monographs, regimen monographs, appendices and symptom management information contained in the Formulary will change as they are reviewed and revised on a periodic basis. The date of last revision will be visible on each page of the monograph and regimen. Since standards of usage are constantly evolving, it is advised that the Formulary not be used as the sole source of information. It is strongly recommended that original references or product monograph be consulted prior to using a chemotherapy regimen for the first time.

Some Formulary documents, such as the medication information sheets, regimen information sheets and symptom management information (for patients), are intended for patients. Patients should always consult with their healthcare provider if they have questions regarding any information set out in the Formulary documents.

While care has been taken in the preparation of the information contained in the Formulary, such information is provided on an "as-is" basis, without any representation, warranty, or condition, whether express, or implied, statutory or otherwise, as to the information's quality, accuracy, currency, completeness, or reliability.

CCO and the Formulary's content providers shall have no liability, whether direct, indirect, consequential, contingent, special, or incidental, related to or arising from the information in the Formulary or its use thereof, whether based on breach of contract or tort (including negligence), and even if advised of the possibility thereof. Anyone using the information in the Formulary does so at his or her own risk, and by using such information, agrees to indemnify CCO and its content providers from any and all liability, loss, damages, costs and expenses (including legal fees and expenses) arising from such person's use of the information in the Formulary.



back to top