Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Bortezomib - In Combination with Lenalidomide and Dexamethasone for Previously Untreated Multiple Myeloma Without Intent for Stem Cell Transplantation

(This form should be completed before the first dose is dispensed.)

1. Patient Profile

* Surname: .....
* Given Name: .....
* OHIN: ..... * Chart Number: .....
* Postal Code: .....
* Height (cm): ..... * Weight (kg): .....
* BSA (m^2): ..... * Gender: ○ Male ○ Female ○ Other
* Date of Birth: ....
  Day Month Year
* Site:
* Attending Physician (MRP- Most Responsible Physician): .....

Requested Prior Approval ☐ Yes * Patient on Clinical Trial ○ Yes ○ No

Other (specify): .....

Specify Arm:
○ Standard of care arm ○ Experimental arm
○ Blinded / Unknown

Prior Approval Request

* Select the appropriate prior approval scenario:

- ○ 1-Unknown primary (submit pathology report and clinic note)
- ○ 2-Clinical document review (identify the patient history that needs to be reviewed against eligibility criteria in Additional Comments below)
- ○ 3-Regimen modification - schedule (complete questions a and b)
- ○ 4-Regimen modification - drug substitutions (complete questions a and c)
- ○ 5-Withholding a drug in combination therapy from start of treatment (complete questions d, e and f)
- ○ 6-Maintenance therapy delay (submit clinic note)
- ○ 7-Prior systemic therapy clinical trials (complete question g)
- ○ 8-Modification due to supply interruption/drug shortage
- ○ Other (specify)

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All relevant supporting documentation must be submitted at the time of prior approval. Documentation may include a pathology report, clinic note, and/or CT scans.

a. Co-morbidities / toxicity / justification:

.....

b. Intended regimen schedule: .....

c. Intended regimen: .....

d. Drug(s) to be held: .....

e. Rationale for holding drug(s): .....

f. Intention to introduce drug at a later date? ☐ Yes

g. Prior clinical trial identifier (e.g., NCT ID, trial name) and treatment description (e.g., arm, drug/regimen): .....

h. Anticipated date of first treatment: ....
Day Month Year

i. Additional comments:

2. Eligibility Criteria

a. The patient must meet the following criteria:

- Bortezomib is used in combination with lenalidomide and low-dose dexamethasone (RVd) in patients with newly diagnosed multiple myeloma, good performance status, and in whom stem cell transplantation is not intended. ☐ Yes

3. Baseline Information

a. ECOG Performance Status at the time of enrolment ○ 0 ○ 1 ○ 2

b. Is the patient transitioning from non-publicly funded means (e.g. private payer or compassionate program)? ○ Yes ○ No

c. If yes, how many cycles did the patient complete prior to the transition?
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7

4. Funded Dose

Bortezomib 1.3 mg/m^2 or 1.5 mg/m^2 intravenously (IV) or subcutaneously (SC) days 1, 8, and 15, in combination with lenalidomide and dexamethasone, every 3 weeks for 8 cycles.

Bortezomib can also be given at 1.3 mg/m^2 IV or SC on days 1, 4, 8, and 11 every 3 weeks.

All cycles of bortezomib are given with lenalidomide and dexamethasone. Starting with cycle 9 onwards, lenalidomide and dexamethasone should be continued as maintenance until disease progression or unacceptable toxicity.

ST-QBP regimen code: BORTDEXALENA

5. Notes

1. Please refer to the Ontario Drug Benefit Formulary for the Limited Use criteria for lenalidomide.
2. Regardless of the chosen administration schedule (i.e. once weekly or twice weekly), bortezomib will be funded for a total of eight 3-week cycles.

3. Patients who are refractory to lenalidomide will not be eligible for daratumumab or carfilzomib-based triplets that are used in combination with lenalidomide.

4. Patients who start treatment and are subsequently deemed transplant ineligible may complete induction therapy under this policy (up to 8 cycles of bortezomib-based therapy in total).

5. On a time-limited basis (until March 16, 2021), patients who initiated lenalidomide and dexamethasone therapy for previously untreated multiple myeloma in the previous 3 months may add bortezomib to their treatment regimen provided the patient's disease has not progressed on lenalidomide and dexamethasone.

6. Patients who require treatment interruptions, but have not progressed, may resume therapy at a later date to complete up to 8 cycles of bortezomib (in combination with lenalidomide and dexamethasone).

6. FAQs

i. **My patient is currently receiving bortezomib through non-publicly funded means. Can my patient be transitioned over to receive funding through the New Drug Funding Program (NDFP)?**

Provided the funding criteria were met at the time of treatment initiation and the patient's disease has not progressed, your patient may be eligible for continued coverage of bortezomib through NDFP. Please submit as a prior approval request including the most recent clinic note (outlining the response to bortezomib therapy, if able to assess). Funding for bortezomib is for a total of 8 cycles, regardless of the funding source.

ii. **My patient is intolerant to part of the regimen. Can they complete induction therapy with the remaining agents?**

Patients who initiate triplet therapy with bortezomib, lenalidomide and dexamethasone who subsequently develop intolerance to one agent may complete induction therapy with the remaining agents. Please note that bortezomib and lenalidomide are not funded as single agents. Switches to other bortezomib-based regimens may be considered by NDFP (under the policy titled 'Bortezomib - Previously Untreated - Multiple Myeloma') if the toxicity is not caused by bortezomib.

iii. **I am not sure if my patient will be able to tolerate bortezomib in combination with lenalidomide and dexamethasone. Can I start with bortezomib (with or without dexamethasone) and add lenalidomide at a later date?**

Bortezomib may be funded for up to 3 cycles without lenalidomide under this policy to assess for tolerance. If lenalidomide and dexamethasone are used initially, bortezomib must be added within the first 3 cycles if the intended treatment regimen is bortezomib in combination with lenalidomide and dexamethasone. These regimen modifications must be submitted as Prior Approvals in eClaims.

iv. **My patient started lenalidomide and dexamethasone for previously untreated transplant-ineligible multiple myeloma before the effective funding date. Can I add bortezomib to the patient's treatment?**

On a time-limited basis (until March 16, 2021), patients who initiated lenalidomide and dexamethasone therapy for previously untreated multiple myeloma in the previous 3 months may add bortezomib to their treatment regimen provided the patient's disease has not progressed on lenalidomide and dexamethasone.

v. **My patient was initially a transplant candidate but is no longer eligible after initiating treatment. Can my patient complete induction treatment with this regimen?**

Patients who start treatment and are subsequently deemed to be transplant ineligible may complete induction therapy under this policy to complete 8 cycles of bortezomib-based therapy.

7. Supporting Documents

None required at the time of enrolment.

In the event of an audit, the following should be available to document eligibility:

- Clinic note(s) and pathology report(s) confirming multiple myeloma diagnosis and transplant ineligibility.

Signature of Attending Physician (MRP- Most Responsible Physician): .....

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Day Month Year

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