Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Bortezomib - In Combination with Selinexor and Dexamethasone for Previously Treated Multiple Myeloma

(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

Specify Trial:
○ Clinical Trial 1 ○ Clinical Trial 2
○ Clinical Trial 3 ○ Other

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

Bortezomib is used in combination with selinexor and dexamethasone (SVd) for the treatment of adult patients with histologically confirmed multiple myeloma who have received at least one prior therapy. ☐ Yes

3. Baseline Information

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

b. Is the patient transitioning from a private pay or compassionate program for bortezomib? ○ Yes ○ No

c. If yes, please indicate the funding source
○ Private payer
○ Manufacturer patient support program

d. If yes, please indicate the date of the last administered dose
Day Month Year

4. Funded Dose

Bortezomib 1.3 mg/m^2 subcutaneously (SC) or intravenously (IV) on days 1, 8, 15, and 22 in combination with selinexor and dexamethasone administered on an every 35-day cycle.

Treatment should continue until disease progression or unacceptable toxicity, whichever comes first.

[ST-QBP regimen code: BORTDEXASELI]

5. Notes

1. Bortezomib (as part of SVd) is only funded in the second line or later setting provided all other eligibility criteria are met, including drug sensitivity.

2. Patients with plasma cell leukemia or systemic light chain amyloidosis are eligible for funding of bortezomib (as part of SVd) provided all other eligibility criteria are met.

3. Prior proteasome inhibitor (PI) therapy is permitted provided:
    - The patient had a PI treatment-free interval of at least 6 months before the start of SVd; AND
    - Achieved at least a partial response (PR) with prior bortezomib (at any time), and at least a PR during the last PI therapy (alone or in combination); AND
    - The patient did not discontinue bortezomib due to grade 3 or higher toxicity.

4. Completion of this form is for funding of bortezomib only. Please refer to the Ministry of Health's Exceptional Access Program for full funding criteria for selinexor. Please check that your patient will be eligible for benefits under the Ontario Drug Benefit Program. Some patients may require registration into the Trillium Drug Program.

5. Patients who may have been accessing NDFP-funded bortezomib (as part of SVd) with non-publicly funded selinexor are to submit a new enrolment form under this policy.

6. Additional observation in the form of ophthalmic examination(s) may be required for patients being treated with selinexor.

6. FAQs

1. **My patient is currently receiving bortezomib through non-publicly funded means (e.g., patient support program, private insurance). Can my patient be transitioned to receive funding for bortezomib through the New Drug Funding Program (NDFP)?**

   Provided the eligibility 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 the NDFP.

2. **What is the process for transitioning my patient from a non-publicly funded program to NDFP funding?**

   If your patient meets all of the eligibility criteria outlined in this policy, please submit as a regular eClaims enrolment.

   Prior approval requests are reserved for instances where there is clinical uncertainty on eligibility. In these circumstances, please specify your reason(s) for uncertainty and upload the following:
    - A clinic note and imaging (if applicable) from treatment initiation, and
    - The most recent clinic note and imaging (if applicable).

Supporting Documents

None required at time of enrolment.
In the event of an audit or upon request, the following should be available to document eligibility:
- Clinic note(s) documenting prior treatment history including response to prior bortezomib and/or PI use (if applicable).
- Pathology report(s) demonstrating histologically confirmed multiple myeloma, plasma cell leukemia or systemic light chain amyloidosis.

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

....
Day Month Year

Form 1036