

Bortezomib - Previously Untreated Transplant Ineligible Mantle Cell Lymphoma

(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 (m²): * 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:

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b. Intended regimen schedule:

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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):

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h. Anticipated date of first treatment:

.....
Day Month Year

i. Additional comments:

2. Eligibility Criteria

The patient must meet the following criteria:

Bortezomib (in combination with rituximab, cyclophosphamide, doxorubicin, and prednisone as part of VR-CAP) is used for the treatment of patients with previously untreated mantle cell lymphoma who are ineligible for an autologous stem cell transplant. ☐ 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? ☐ Yes ☐ No

d. If yes to 3b, how many doses of once weekly bortezomib did the patient receive prior to transition?

☐ N/A ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8
☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15 ☐ 16 ☐ 17
☐ 18 ☐ 19 ☐ 20 ☐ 21 ☐ 22 ☐ 23 ☐ 24

c. If yes to 3b, how many doses of twice weekly bortezomib did the patient receive prior to transition?

☐ N/A ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8
☐ 9 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15 ☐ 16 ☐ 17
☐ 18 ☐ 19 ☐ 20 ☐ 21 ☐ 22 ☐ 23 ☐ 24 ☐ 25 ☐ 26
☐ 27 ☐ 28 ☐ 29 ☐ 30 ☐ 31 ☐ 32

4. Funded Dose

Bortezomib 1.3 mg/m² intravenously (IV) or subcutaneously (SC) on days 1, 4, 8, and 11 every 21 days OR
Bortezomib 1.3 to 1.5 mg/m² IV or SC on days 1, 8, and 15 every 21 days.

[ST-QBP regimen code: BORTCYCDOXPRED+R]

Treatment should be continued until disease progression, unacceptable toxicity or up to a maximum of 8 cycles, whichever occurs first.

Please select the approved dosing schedule for bortezomib (used as part of VR-CAP): ☐ Once Weekly
☐ Twice Weekly

5. Notes

1. Enrolment in this policy is for the funding of bortezomib only. For rituximab funding, please complete the policy "*Rituximab (Biosimilar IV) and Rituximab SC in Combination with Chemotherapy - Indolent B-cell Lymphoma.*"

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 (as part of VR-CAP) through NDFP. Please submit as a prior approval request including the most recent clinic note outlining the response to treatment (if able to assess).

- ii. **My patient is currently being treated with R-CHOP or R-Bendamustine for mantle cell lymphoma. Due to toxicities or preference, can my patient be switched to receive VR-CAP?**

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 bortezomib (as part of VR-CAP) funding through NDFP. Please submit a prior approval request including the most recent clinic note outlining the response to treatment (if able to assess).

Supporting Documents

None required at time of enrolment.

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

- Clinic note(s) confirming treatment history and that the patient is transplant ineligible.

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

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Day Month Year