

Carfilzomib (Doublet Therapy) - In Combination with Dexamethasone for Relapsed Multiple Myeloma

(This form must 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
- 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:

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:

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2. Eligibility Criteria

- Carfilzomib is used in combination with dexamethasone for patients with relapsed myeloma with a good performance status who have received one to three prior treatments. Yes

3. Baseline Information

- a. ECOG Performance Status at the time of enrolment 0 1
 2
- b. Number of prior treatments: 1 2
 3
- c. Is the patient transitioning from a private payer or compassionate program? Yes No
- d. If yes, please indicate the total number of milligrams the patient received prior to transitioning to NDFP funding:

4. Funded Dose

Cycle 1 - Carfilzomib 20 mg/m² intravenously (IV) days 1 and 2, followed by Carfilzomib 56 mg/m² IV days 8, 9, 15, 16
Cycle 2 and beyond - Carfilzomib 56 mg/m² days IV 1, 2, 8, 9, 15, 16

Alternative dosing schedule:

Cycle 1 - Carfilzomib 20 mg/m² IV on day 1, followed by Carfilzomib 70 mg/m² IV on days 8 and 15
Cycle 2 and beyond - Carfilzomib 70 mg/m² IV on days 1, 8, and 15

1 cycle = 28 days

[ST-QBP regimen code: CARFDEXA, CARFDEXA(W)]

5. Notes

1. Re-treatment with carfilzomib is not publicly funded (i.e. if patients previously received carfilzomib, regardless of funding source, they are not eligible to receive carfilzomib under this policy).
2. Carfilzomib must be initiated with dexamethasone to be eligible for funding.

6. FAQs

1. **My patient completed 18 cycles of carfilzomib as part of triplet therapy with good response, but is now showing signs of relapse. Can I now treat with carfilzomib and dexamethasone?**

The New Drug Funding Program (NDFP) will fund one course of treatment with carfilzomib for each patient with relapsed myeloma, either as part of a doublet or triplet, for carfilzomib-naïve patients. If a patient completes 18 cycles of carfilzomib as part of triplet therapy, regardless of funding source, they will not be eligible for further treatments with carfilzomib at the point of relapse.

7. Supporting Documents

None required at the time of enrolment.

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

- Clinic notes detailing previous treatment history.

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

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Day Month Year