Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Isatuximab and Carfilzomib - In Combination with Dexamethasone for Relapsed or Refractory 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

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)

.....

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

Isatuximab and carfilzomib are used in combination with dexamethasone (IsaKd) in adult patients* with relapsed or refractory multiple myeloma (MM) who have received at least one prior line of therapy. ☐ Yes

*Patients should have evaluable disease and a good performance status.

*Patients must not:

- Be refractory to an anti-CD38 monoclonal antibody, OR
- Be refractory to carfilzomib, OR
- Have a left ventricular ejection fraction less than 40%.

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

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

Isatuximab

Cycle 1: 10 mg/kg intravenously (IV) on days 1, 8, 15, and 22
Cycle 2 and onwards: 10 mg/kg IV on days 1 and 15

Please select the dosing schedule for carfilzomib:

○ Cycle 1: 20 mg/m^2 IV on days 1 and 2, then 56 mg/m^2 IV on days 8, 9, 15 and 16
Cycle 2 and onwards: 56 mg/m^2 IV on days 1, 2, 8, 9, 15, and 16

OR

○ Cycle 1: 20 mg/m^2 IV on day 1, then 70 mg/m^2 IV on days 8 and 15
Cycle 2 and onwards: 70 mg/m^2 IV on days 1, 8, and 15

[1 cycle = 28 days]

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

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

5. Notes

1. Completion of this form will enroll the patient in both isatuximab and carfilzomib.

2. Refractory disease is defined as:
    - Disease progression within 60 days of any dose of therapy, OR
    - Disease progression while on therapy, OR
    - Failure to achieve at least a minimal response while on therapy.

3. The following patients are eligible for funding, provided all other eligibility criteria are met:
    - Patients who only have measurable disease using serum free light chains;
    - Patients who have primary refractory multiple myeloma;
    - Patients who have amyloidosis concomitant with multiple myeloma.

4. Patients will only be eligible for one line of isatuximab-based therapy (in combination with carfilzomib and dexamethasone or in combination with pomalidomide and dexamethasone) provided all other eligibility criteria are met.

6. FAQs

1. **My patient is currently receiving isatuximab and carfilzomib through non-publicly funded means (e.g., patient support program, private insurance). Can my patient be transitioned to receive funding for isatuximab and carfilzomib 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 through NDFP.

   Patients who meet the eligibility criteria may be transitioned to NDFP funding through a regular eClaims enrolment. If there is clinical uncertainty regarding eligibility, these requests may be submitted as a prior approval including a clinic note from the time of initiation as well as the most recent clinic note outlining the response to treatment (if able to assess).

   Of note, patients enrolled in the manufacturer's Patient Support Program (PSP) will continue to receive treatment with isatuximab through the PSP until September 6, 2023, inclusive. While these patients may enroll before September 7, 2023, please be aware any treatments submitted to eClaims that were given on or before September 6, 2023, will be denied.

2. **If one of the components of the IsaKd regimen is discontinued, will NDFP continue to provide funding for the remaining medication(s)?**

   If isatuximab, carfilzomib, or dexamethasone requires discontinuation, funding will continue for the remaining component(s) of the regimen.

3. **My patient is currently being treated with carfilzomib and dexamethasone (Kd). Will my patient be eligible for NDFP funding of isatuximab added to Kd?**

   Isatuximab can be added to carfilzomib and dexamethasone provided the patient met the eligibility criteria at the time of treatment initiation and has not progressed. Please submit as a prior approval request under this policy in eClaims 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 or upon request, the following should be available to document eligibility:

- Clinic note(s) outlining patient and treatment history.

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

....
Day Month Year

Form 1021