Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Isatuximab - In Combination with Pomalidomide and 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 is used in combination with pomalidomide and dexamethasone (IsaPd) in adult patients with relapsed or refractory multiple myeloma (MM) who have received at least two prior lines of therapy including lenalidomide and a proteasome inhibitor.* ☐ Yes

Patients must:

- Be refractory to the last line of therapy AND
- Have a good performance status.

Patients must not:

- Be refractory to an anti-CD38 monoclonal antibody.

*Lenalidomide and a proteasome inhibitor may be given as monotherapy or in combination with any prior therapy.

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

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

Cycle 2 and onwards:
Isatuximab 10 mg/kg IV on days 1 and 15

[1 cycle = 28 days]

Isatuximab is given in combination with pomalidomide and dexamethasone.

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

[ST-QBP regimen code(s): DEXAPOMA+ISAT]

5. Notes

1. Enrolment in this policy is for isatuximab only. Please refer to the Ministry of Health for the full reimbursement criteria of pomalidomide.

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 have primary refractory multiple myeloma;
    - Patients with free light chain measurable disease only;
    - Patients with known high risk cytogenetics [del(17p), t(4;14), or t(14;16) by fluorescence in situ hybridization (FISH)].

4. Patients with primary amyloidosis are not eligible.

5. Patients will only be eligible for one line of an 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 through non-publicly funded means (e.g., patient support program, private insurance). Can my patient be transitioned to receive funding for isatuximab 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 isatuximab 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. **My patient is currently being treated with pomalidomide and dexamethasone (Pd). Will my patient be eligible for NDFP funding of isatuximab added to Pd?**

   Isatuximab can be added to pomalidomide and dexamethasone provided the patient met the eligibility criteria at the time of treatment initiation and has not progressed. Please submit a prior approval request in eClaims including a clinic note from treatment initiation and the most recent clinic note outlining the response to treatment, if able to assess.

3. **My patient was treated with first line lenalidomide, bortezomib, and dexamethasone (RVd) but is resistant or refractory to lenalidomide and bortezomib. Would my patient be eligible for NDFP funding of isatuximab if given second line as IsaPd?**

   Although IsaPd is indicated to be given after two or more lines of therapy, if a patient is resistant or refractory to first line lenalidomide and bortezomib as part of RVd, they are eligible for funding of second line isatuximab as part of IsaPd.

4. **In cases of pomalidomide intolerance or discontinuation, can isatuximab and dexamethasone be continued?**

   If pomalidomide requires discontinuation, funding will continue for the remaining component(s) of the regimen.

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