Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Daratumumab - In Combination with Lenalidomide and 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 (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 (comple 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

The patient must meet the following criteria:

Daratumumab is used in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma with good performance status 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. Please select the number of prior treatments ○ 1 ○ 2 ○ 3 or more

c. Has the patient been previously treated with lenalidomide or is currently on lenalidomide? ○ Yes ○ No

4. Funded Dose

Subcutaneous (SC):
Cycles 1 to 2 – daratumumab 1800mg SC once per week for a total of 8 doses;
Cycles 3 to 6 – daratumumab 1800mg SC once every 2 weeks for a total of 8 doses;
Cycle 7 and beyond – daratumumab 1800mg SC once every 4 weeks.

Or

Intravenous (IV)
Cycles 1 to 2 – daratumumab 16 mg/kg IV once per week for a total of 8 doses;
Cycles 3 to 6 – daratumumab 16 mg/kg IV once every 2 weeks for a total of 8 doses;
Cycle 7 and beyond – daratumumab 16 mg/kg IV once every 4 weeks.

Daratumumab is funded when used in combination with lenalidomide and dexamethasone.

All cycles are given in combination with lenalidomide and dexamethasone as part of an every 4-week treatment cycle.

Treatment with daratumumab should be continued until disease progression or unacceptable toxicity.

[ST-QBP regimen codes: DARADEXALENA or DARADEXALENA(SC)]

5. Notes

1. Daratumumab must be initiated with lenalidomide and dexamethasone to be eligible for funding. No additional anti-myeloma therapies are permitted other than those used as part of this triplet.

2. CCO will fund one novel triplet therapy for relapsed multiple myeloma (either daratumumab-based or carfilzomib-based). Patients who experience toxicity to one of these triplets may switch once to another triplet within the first 3 months of starting treatment.

3. Patients who were previously treated with lenalidomide or are currently on lenalidomide must meet all of the following criteria to be eligible for the addition of daratumumab:
    - Lenalidomide was not discontinued due to adverse events
    - The patient's disease is not refractory* to lenalidomide.

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

4. Patients whose disease is refractory to both lenalidomide and bortezomib are not eligible for publicly funded daratumumab.

5. The use of daratumumab as maintenance or consolidation post-autologous stem cell transplantation is not eligible for NDFP funding under this policy.

7. FAQs

i. My patient is currently receiving daratumumab through private 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 daratumumab through NDFP. Please submit as a prior approval request in eClaims including the most recent clinic note outlining the response to treatment, if able to assess, and the number of daratumumab treatments received to date.

ii. My patient initiated lenalidomide/dexamethasone without daratumumab. Can I add daratumumab to the treatment regimen at a later date?

Patients who initiate therapy with lenalidomide/dexamethasone in the relapsed setting may be eligible to add daratumumab to the treatment regimen at a later date, provided all funding criteria are met and the patient has not progressed on lenalidomide.

iii. My patient is currently on lenalidomide-based therapy but is showing signs of relapse. Would they be eligible for a daratumumab-based triplet?

Patients who relapse on any dose of lenalidomide (including maintenance) are not eligible for daratumumab as part of this policy.

iv. Will the New Drug Funding Program (NDFP) allow split dosing over two days for the initial dose of daratumumab?

NDFP can support funding the initial dose as either a single dose infusion (16 mg/kg IV on Day 1) or a split dose infusion (8 mg/kg IV on Days 1 and 2) to allow for scheduling flexibility.

v. Can patients previously on carfilzomib-lenalidomide-dexamethasone (KRd) who then switched to a daratumumab-based triplet, subsequently access carfilzomib-dexamethasone (Kd) after disease progression on daratumumab?

If a carfilzomib-based triplet was switched to a daratumumab-based triplet for reasons other than disease progression, the patient may be eligible for downstream carfilzomib upon progression provided all eligibility criteria are met.

vi. What documentation is required if my patient is on privately funded daratumumab and would like to transition to publicly funded daratumumab?

At the point of enrolment, please upload a recent clinic note indicating the number of completed cycles of privately funded daratumumab, along with the patient's response to treatment. If there are specific uncertainties regarding a patient's eligibility to transition, please submit as an eClaims Prior Approval request with the aforementioned documentation to allow for review.

6. Supporting Documents

If the patient does not have previous bortezomib treatments in eClaims, please upload clinic notes indicating the previous treatment history, including the reason for treatment discontinuation.

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

- Clinic notes indicating treatment history, including the reason for discontinuing previous treatment.

To ensure reimbursement of your claim, both the completed enrolment form and a copy of the required documentation (where applicable) must be submitted through CCO e-Claims.

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

....
Day Month Year

Form 969