Ontario Health | Santé Ontario

eClaims
Demandes de remboursement en ligne

Eligibility Form

Daratumumab - In Combination with Bortezomib 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 bortezomib 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

4. Funded Dose

Subcutaneous (SC):
Cycles 1 to 3 – daratumumab 1800mg SC once per week for a total of 9 doses;
Cycles 4 to 8 – daratumumab 1800mg SC once every 3 weeks for a total of 5 doses;
Cycle 9 and onwards – daratumumab 1800mg SC once every 4 weeks.

Or

Intravenous (IV)
Cycles 1 to 3 – daratumumab 16 mg/kg IV once per week for a total of 9 doses;
Cycles 4 to 8 – daratumumab 16 mg/kg IV once every 3 weeks for a total of 5 doses;
Cycle 9 and onwards – daratumumab 16 mg/kg IV once every 4 weeks.

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

Cycles 1-8 are given in combination with bortezomib and dexamethasone as part of an every 3-week treatment cycle.

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

[ST-QBP regimen codes: BORTDEXADARA or BORTDEXADARA(SC) for cycles 1-8, DARA(MNT) or DARA(MNT-SC) for cycle 9 and beyond]

5. Notes

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

2. Patients who start with bortezomib/dexamethasone for relapsed multiple myeloma may add daratumumab to the treatment regimen at a later date, provided the patient meets all criteria at the point of daratumumab addition and there has been no disease progression while on treatment.

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

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

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

1. **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.

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

   Patients who relapse on any dose of bortezomib are not eligible for daratumumab as part of this policy.

3. **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.

4. **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 provided all NDFP eligibility criteria are met.

5. **My patient is refractory to a non-bortezomib proteasome inhibitor, and I would like to treat them with daratumumab-bortezomib-dexamethasone (DVd). Is my patient eligible for funding?**

   Patients whose disease is refractory to any proteasome inhibitor (including bortezomib and carfilzomib) are not eligible for funding for the DVd regimen.

6. **Is once-weekly bortezomib dosing an acceptable alternative schedule as part of the daratumumab-bortezomib-dexamethasone (DVd) regimen?**

   The NDFP can accommodate daratumumab funding as part of this regimen with any evidence-informed Systemic Treatment Quality-Based Procedure (ST-QBP) bortezomib dosing schedule.

6. 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 treatment history/response including response to prior bortezomib-based therapy (if applicable).

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

....
Day Month Year

Form 1134