Ontario Health / Santé Ontario

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Demandes de remboursement en ligne

Eligibility Form

Daratumumab in Combination with a Bortezomib-Based Regimen for Newly Diagnosed Transplant Ineligible 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

The patient must meet the following criteria:

Daratumumab is used in combination with either bortezomib, melphalan and prednisone (DVMP) or cyclophosphamide, bortezomib and dexamethasone (DCyBorD) for the treatment of patients with newly diagnosed multiple myeloma who are not suitable for autologous stem cell transplant and have good performance status. ☐ Yes

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, how many daratumumab doses did the patient have prior to the transition? .....

d. Is the patient transitioning from another first line regimen? ○ Yes ○ No

e. If yes to 3d, specify the regimen ○ Rd ○ CyBoRD ○ VMP ○ RVD ○ Other

f. If "other", please specify .....

g. Patient will receive daratumumab in combination with
○ CyBorD
○ VMP

4. Funded Dose

Daratumumab if used in combination with CyBorD (1 cycle = 4 weeks)
Subcutaneous (SC)
Cycles 1 and 2 – daratumumab 1800mg SC on Days 1, 8, 15, 22;
Cycles 3 to 6 – daratumumab 1800mg SC on Days 1 and 15;
Cycles 7 and beyond – daratumumab 1800mg SC on Day 1

Or

Intravenous (IV)
Cycles 1 and 2 – daratumumab 16mg/kg on Days 1, 8, 15, 22;
Cycles 3 to 6 – daratumumab 16mg/kg on Days 1 and 15;
Cycles 7 and beyond – daratumumab 16mg/kg on Day 1

Daratumumab if used in combination with VMP
Subcutaneous (SC)
Cycle 1 – daratumumab 1800mg SC on Days 1, 8, 15, 22, 29, and 36 of a 6-week cycle
Cycles 2 to 9 – daratumumab 1800mg SC on Days 1 and 22 every 6 weeks
Cycles 10 and beyond – daratumumab 1800mg SC on Day 1 every 4 weeks

Intravenous (IV)
Cycles 1 – Daratumumab 16mg/kg IV on Days 1, 8, 15, 22, 29, and 36 of a 6-week cycle;
Cycles 2 to 9 – Daratumumab 16mg/kg IV on Days 1 and 22 every 6 weeks;
Cycles 10 and beyond – Daratumumab 16mg/kg IV on Day 1 every 4 weeks

Daratumumab may continue as a single agent following completion of the bortezomib-based regimen, until unacceptable toxicity or disease progression.

ST-QBP regimen codes:
Daratumumab in combination with VMP (or BMP) [DVMP] – ST-QBP codes - (BMP+DARA, DARA(MNT), BMP+DARA(SC), DARA(MNT-SC))

Daratumumab in combination with CyBorD [DCyBorD] – ST-QBP codes CYBORD+DARA, DARA(MNT), CYBORD+DARA(SC), DARA(MNT-SC))

5. Notes

1. Daratumumab must be used with either VMP or CyBorD to be eligible for funding. No additional anti-myeloma therapies are permitted other than those listed above.

2. Daratumumab is not funded if used
    - for the treatment of monoclonal gammopathy of undetermined significance (MGUS), or smoldering multiple myeloma, or amyloidosis without evidence of concomitant myeloma;
    - as maintenance or consolidation post autologous stem cell transplant.

3. Slow gradual biochemical changes, that otherwise would qualify as progression, may not be a reason to change therapy in clinical practice, unless coupled with signs of clinical evidence of progression (such as increased pain, or increased need for supportive measures, or renal failure). The decision to continue daratumumab or move to the next line of therapy is at the discretion of the treating physician.

4. When daratumumab is used in combination with a bortezomib-based regimen for newly diagnosed transplant eligible multiple myeloma, the cost of bortezomib is funded through the Systemic Treatment Quality-Based Procedure (ST-QBP) and is included in the band level pricing.

6. FAQs

1. **My patient is currently receiving daratumumab through private means. Can my patient be transitioned to receive funding through the New Drug Funding Program?**

   Provided the funding criteria were met at the time of treatment initiation and the patient's disease has not yet progressed, your patient may be eligible for continued coverage of daratumumab through NDFP. Please submit as a prior approval request with clinic notes that document the patient's clinical and treatment history, including confirmation that the patient is not eligible for autologous stem cell transplant and that the patient's disease has not yet progressed.

2. **My patient is currently on VMP or CyBorD for previously untreated transplant ineligible myeloma. Can daratumumab be added?**

   NDFP will fund the addition of daratumumab to VMP or CyBorD in patients who recently initiated treatment provided the patient is not experiencing disease progression on a bortezomib-based regimen. Please submit as a prior approval request with clinic notes that document the patient's clinical and treatment history, including confirmation that the patient is not eligible for autologous stem cell transplant and that the patient's disease has not yet progressed.

3. **My patient is currently on another bortezomib-based regimen for previously untreated transplant ineligible myeloma. Can I switch my patient to daratumumab?**

   NDFP will fund the switch to daratumumab provided the patient's disease has not yet progressed and all other funding criteria are met. Please submit as a prior approval request with clinic notes that document the patient's clinical and treatment history, including confirmation that the patient is not eligible for autologous stem cell transplant and that the patient's disease has not yet progressed.

4. **My patient's disease is showing signs of biochemical progression. Can I add cyclophosphamide to D-VMP?**

   Daratumumab will not be funded if cyclophosphamide is added due to disease progression. No additional anti-myeloma therapies are permitted other than those used as part of this 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) and pathology report(s) confirming multiple myeloma diagnosis and transplant ineligibility.

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

....
Day Month Year

Form 1136