Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Daratumumab and Bortezomib in combination with Cyclophosphamide and Dexamethasone - Previously Untreated Light Chain (AL) Amyloidosis

(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 and bortezomib (in combination with cyclophosphamide and dexamethasone) is used for the treatment of adult patients with previously untreated light chain (AL) amyloidosis and who have a 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 doses of daratumumab did the patient have prior to the transition?

○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7	○ 8	○ 9
○ 10	○ 11	○ 12	○ 13	○ 14	○ 15	○ 16	○ 17	○ 18
○ 19	○ 20	○ 21	○ 22	○ 23	○ 24	○ 25	○ 26	○ 27
○ 28	○ 29	○ 30	○ 31	○ 32	○ 33			

d. If yes, how many doses of bortezomib did the patient have prior to the transition?

○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7	○ 8	○ 9
○ 10	○ 11	○ 12	○ 13	○ 14	○ 15	○ 16	○ 17	○ 18
○ 19	○ 20	○ 21	○ 22	○ 23				

4. Funded Dose

Cycles 1 to 2:
Daratumumab 1800 mg subcutaneously (SC) on day 1, 8, 15, and 22
Bortezomib 1.3 mg/m^2 SC on day 1, 8, 15, and 22

Cycles 3 to 6:
Daratumumab 1800 mg SC on day 1 and 15
Bortezomib 1.3 mg/m^2 SC on day 1, 8, 15, and 22

Cycles 7 to 24:
Daratumumab 1800 mg SC on day 1

(1 cycle = 28 days)

For cycles 1 to 6, daratumumab and bortezomib are administered in combination with cyclophosphamide and dexamethasone. For cycles 7 to 24, daratumumab monotherapy is administered as maintenance.

Treatments will be funded until evidence of hematologic progression or organ decompensation while on treatment, unacceptable toxicity, or up to a maximum of 24 cycles (whichever occurs first).

[ST-QBP regimen codes: CYBORD_DARA(SC) then DARA(MNT-SC)]

5. Notes

1. Completion of this form will enroll the patient in both daratumumab and bortezomib.

2. The patient should demonstrate all of the following:
    a. Histopathologic diagnosis of systemic AL amyloidosis based on detection by immunohistochemistry and polarizing light microscopy of green bi-refringent material in Congo red-stained tissue specimens or characteristic electron microscopy appearance,
    b. Measurable disease by serum M protein greater than or equal to 5 g/L OR abnormal serum free light chain ratio OR difference between involved and uninvolved free light chains (dFLC) greater than or equal to 50 mg/L,
    c. Involvement of at least one organ system,
    d. Adequate hematologic, hepatic, and renal function.

3. Patients previously treated for AL amyloidosis will not be eligible for funding under this policy.

4. Patients with a previous history or current diagnosis of multiple myeloma (including the presence of lytic bone disease, plasmacytomas, greater than or equal to 60% plasma cells in bone marrow, or hypercalcemia) will not be eligible for funding under this policy. In addition, patients previously treated for multiple myeloma (including medications that target CD38) will not be eligible for funding.

5. Patients with a planned autologous stem cell transplant (ASCT) during the first 6 cycles of this treatment regimen will not be eligible for funding.

6. Patients with non-AL amyloidosis will not be eligible for funding.

7. Patients with advanced cardiac disease (Mayo Cardiac Stage IIIB or NYHA Classification IIIB or IV heart failure) are eligible for funding at the discretion of the treating clinician.

6. FAQs

i. **My patient is currently receiving daratumumab, cyclophosphamide, bortezomib, and dexamethasone (DCyBorD) for AL amyloidosis. The daratumumab and bortezomib is paid for by alternate funding sources (e.g. patient support program, private insurance, hospital budget, etc.). Can my patient be transitioned to receive public funding under 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 NDFP funding. Please submit a prior authorization request including clinic notes from initiation of therapy and from the most recent clinic visit, specifying the number of daratumumab and bortezomib doses received to date. Funding is for a maximum of 24 cycles of daratumumab, regardless of funding source.

ii. **My patient is currently being treated with cyclophosphamide, bortezomib, and dexamethasone (CyBorD) for AL amyloidosis and is progressing/not demonstrating a response from initiation of treatment. Will my patient be eligible for NDFP funding if daratumumab is added to their CyBorD regimen? What is the time frame for adding daratumumab to CyBorD?**

Daratumumab may be added to a patient's current CyBorD regimen depending on the judgement of the treating clinician. Please submit a prior approval request including clinic note(s) outlining the reason for adding daratumumab and the treatment response to CyBorD (if able to assess). The time frame for adding daratumumab is up to the judgement of the clinician.

iii. **My patient recently completed all cycles of CyBorD and their disease has not yet progressed. Will my patient be eligible for NDFP funding of daratumumab maintenance?**

Patients who achieve an adequate response on CyBorD do not need to be treated with daratumumab as maintenance therapy.

iv. **My patient received an autologous stem cell transplant (ASCT) after DCyBorD. Will my patient be eligible for daratumumab maintenance therapy post-ASCT?**

Patients who receive an ASCT after DCyBorD will not be eligible for funding of daratumumab maintenance post-ASCT.

v. **My patient received 6 cycles of DCyBorD, completed daratumumab maintenance, and then subsequently relapsed. Will my patient be eligible for retreatment with DCyBorD followed by daratumumab maintenance?**

This policy is for patients with previously untreated light chain (AL) amyloidosis. There is no evidence to support retreatment at relapse.

vi. **My patient is unable to tolerate the subcutaneous formulation of daratumumab. Can the intravenous formulation be administered and what is the equivalent dosing?**

The intravenous formulation of daratumumab can be administered in place of the subcutaneous formulation at a dose of 16 mg/kg at the same dosing schedule.

Supporting Documents

The following clinical document(s) must be uploaded at the time of enrolment:

- Pathology report confirming systemic AL amyloidosis.

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

- Involvement of at least one organ system and lab work demonstrating measurable disease
- Clinic note(s) outlining the patient's baseline characteristics and treatment history
- Clinic note(s) discussing response to therapy (if applicable).

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

....
Day Month Year

Form 970