Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Blinatumomab - Minimal Residual Disease (MRD)-Positive B-cell Precursor Acute Lymphoblastic Leukemia

(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)

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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:

Blinatumomab is used for the treatment of adult and pediatric patients with Philadelphia chromosome-negative (Ph-), CD19 positive (CD19+), B-cell precursor acute lymphoblastic leukemia (BCP-ALL) who are in first or second hematologic complete remission (CR) and are minimal residual disease positive (MRD+). ☐ Yes

MRD+ disease is defined as MRD detected at a level greater than or equal to 0.1% (i.e., $\geq 10^{-3}$)

Patients should have received, over the course of their treatment for BCP-ALL, a minimum of 3 intensive chemotherapy blocks of a treatment regimen that is age-appropriate and given with curative intent before proceeding to blinatumomab therapy.

3. Baseline Information

a. ECOG Performance Status at the time of enrolment ○ 0 ○ 1 ○ 2

b. Complete Remission status ○ First ○ Second

4. Funded Dose

Funded dose for patients 45 kg or over:
Blinatumomab 28 mcg/day for days 1-28, followed by a 14-day treatment-free interval.

Funded dose for patients under 45 kg:
Blinatumomab 15 mcg/m^2/day for 28 days, followed by a 14-day treatment-free interval.

Treatment should be continued until unacceptable toxicity, hematologic relapse, MRD relapse, treatment with hematopoietic stem cell transplant (HSCT), or up to the completion of 4 cycles. Maintenance or consolidation therapy after HSCT is not funded.

[ST-QBP regimen code: BLIN]

5. Notes

1. Patients treated with 4 cycles of blinatumomab under this policy will not be eligible for blinatumomab retreatment for relapsed ALL.
2. Patients with Philadelphia chromosome-positive ALL, MRD negative or unknown status are not eligible for blinatumomab under this policy.
3. NDFP will provide coverage of blinatumomab in both the inpatient and outpatient settings, provided that funding criteria are met.
4. NDFP recognizes that the amount of drug used to prepare the IV solution for infusion exceeds the amount that is infused into the patient due to the unique preparation method (i.e., an “overfill” of drug is required to account for the priming of the IV line and to ensure that the patient will receive the prescribed dose of blinatumomab.). This “overfill” amount will be automatically captured in eClaims according to the treatment doses submitted.

6. FAQs

i. **My patient is currently receiving blinatumomab through non-publicly funded 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 blinatumomab through the New Drug Funding Program. Please note that the funding is for a total of 4 cycles of blinatumomab, regardless of the funding source.

ii. **My patient has relapsed after treatment with blinatumomab under this policy. Can I treat my patient with inotuzmab ozogamicin for relapsed ALL?**

Provided all other eligibility criteria are met, the NDFP can fund sequencing of blinatumomab and inotuzumab ozogamicin in curative situations for relapsed Ph- ALL. Curative situation is defined as a goal to proceed with cellular therapy if response can be achieved.

iii. **My patient proceeded to cellular therapy without completing 4 cycles of blinatumomab for MRD+ disease. Can I re-treat with blinatumomab at the time of relapse?**

Provided all other eligibility criteria are met, the NDFP can fund re-treatment with blinatumomab for relapsed ALL in curative situations for relapsed Ph- ALL if fewer than 4 cycles were used for MRD+ BCP-ALL. Curative situation is defined as a goal to proceed with cellular therapy if response can be achieved.

Supporting Documents

Pathology report confirming MRD+ status by a validated test must be uploaded at the time of enrolment.

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

- Clinic notes detailing the patient’s treatment history
- Pathology report indicating Ph- status

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

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Day Month Year