Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Blinatumomab - Relapsed or Refractory Acute Lymphoblastic Leukemia (Ph+ BCP-ALL)

(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 (complete question g)
- ○ 8-Modification due to supply interruption/drug shortage
- ○ 9-Supplemental doses requested
- ○ 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:

- Adult patients with Philadelphia chromosome-positive B-cell precursor acute lymphoblastic leukemia (Ph+ BCP-ALL) who have been treated with at least two prior tyrosine kinase inhibitors (TKIs) and have relapsed or refractory (R/R) disease. ☐ Yes

  Treatment should be for patients with good performance status.

3. Baseline Information

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

b. Please select the prior tyrosine kinase inhibitor(s) used. ☐ Imatinib ☐ Dasatinib ☐ Ponatinib ☐ Other

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

c. Did the patient previously receive an allogeneic transplant? ○ Yes ○ No

4. Funded Dose

Cycle 1:
Blinatumomab 9 mcg/day for days 1-7, followed by blinatumomab 28 mcg/day for 21 days, followed by a 14-day treatment-free interval (ST-QBP regimen code: BLIN).

Cycles 2-5:
Blinatumomab 28 mcg/day for 28 days, followed by a 14-day treatment-free interval (ST-QBP regimen code: BLIN).

Continue treatment until unacceptable toxicity or disease progression to a maximum of 2 cycles for induction and 3 cycles for consolidation.

5. Notes

1. The New Drug Funding Program (NDFP) will provide coverage of blinatumomab in both the inpatient and outpatient settings, provided that funding criteria are met.
2. 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 NDFP. Funding is for 5 total cycles of blinatumomab regardless of funding source.

ii. ***Why will the NDFP fund the cost of blinatumomab in the inpatient setting?***

Funding of the inpatient component is in alignment with the first blinatumomab policy that was implemented in 2017. Due to its associated toxicities, blinatumomab requires administration in specialized cancer centres with a portion of induction therapy given in the inpatient setting, while the remaining administration can occur in the outpatient setting. Given the unique administration requirements, the Ministry was supportive with providing blinatumomab funding for both inpatient and outpatient use.

iii. ***How will claims for the inpatient use be managed in eClaims?***

For some sites with an integrated Computerized Prescriber Order Entry (CPOE) with eClaims, the inpatient/outpatient status will be automatically captured when the claim is submitted; no additional work is required. For other sites, please ensure the treatment setting is selected appropriately on the treatment claim form within the web applications. Once a patient is discharged from hospital, subsequent infusions are started in the outpatient clinic. Sites should select “Outpatient” as the treatment setting as opposed to “Take-Home”.

iv. ***How will the additional drug required in preparation (overfill) be reimbursed?***

Due to the unique preparation and administration of blinatumomab, additional drug is injected into the IV bag in order for the patient to receive the prescribed dose. The overfill dose will be created automatically in eClaims once a prescribed dose is submitted for blinatumomab. The overfill dose reimbursed is calculated according to the infusion preparation information in the product monograph, and will be automatically created as a separate claim under a drug named “blinatumomab_overfill”. The adjudication status of the overfill claim will initially match the adjudication status of the associated blinatumomab treatment claim (i.e., if the blinatumomab claim is Under Review, the overfill claim will also be Under Review). Please note that sites will not be able to manually submit overfill claims.

v. ***Is my patient with Philadelphia chromosome PH+ ALL eligible for treatment with blinatumomab?***

Patients with Ph+ ALL must have failed treatment with at least two prior TKIs before treatment with blinatumomab. Imatinib, (1st generation), dasatinib (2nd generation), and ponatinib (3rd generation) are the currently publicly funded TKIs in ALL when used in accordance with Exceptional Access Program (EAP) reimbursement criteria.

vi. ***Is sequencing of blinatumomab and inotuzumab ozogamicin allowed?***

Provided all other eligibility criteria are met, the NDFP can fund sequencing of blinatumomab and inotuzumab

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

vii. ***My patient experienced significant toxicity and was unable to complete their initial course of blinatumomab. Would they be eligible for inotuzumab ozogamicin?***

Provided all other eligibility criteria are met, your patient may be eligible to switch to inotuzumab ozogamicin if the initial cycle of treatment was unable to be completed due to toxicity reasons.

viii. ***My patient has an overt relapse of Ph+ ALL after first line induction (chemotherapy + TKI). Would they be eligible for blinatumomab?***

NDFP may consider patients with overt relapse of Ph+ BCP-ALL – defined as the need for repeat induction chemotherapy – to move from first line TKI (with standard multi-drug induction chemotherapy) directly to either blinatumomab or inotuzumab ozogamicin instead of requiring a second TKI and further induction chemotherapy. Please submit a Prior Approval request for blinatumomab in eClaims along with relevant documentation for review.

7. Supporting Documents

None required.

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

- Clinic notes documenting previous treatment history.

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

....
Day Month Year