Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

# Blinatumomab - Relapsed or Refractory Pediatric Acute Lymphoblastic Leukemia

(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

## 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:

- For the treatment of pediatric patients with Philadelphia chromosome-negative (Ph-) relapsed or refractory B precursor acute lymphoblastic leukemia (ALL) who are in second or later relapse, or who relapsed after allogeneic hematopoietic stem cell transplant (alloHSCT), or who have refractory disease. Treatment should be in patients with a good performance status and no active central nervous system disease. ☐ Yes

## 3. Baseline Information

a. Blinatumomab is being used for:
- ○ Second or later bone marrow relapse
- ○ Any marrow relapse after allogeneic HSCT
- ○ Disease refractory to other treatments: Patients in first relapse must have failed to achieve a complete remission (CR) following full standard reinduction chemotherapy regimen of at least 4 weeks duration
- ○ Disease refractory to other treatments: Patients who have not achieved a first remission and must have failed a full standard induction regimen

b. Did the patient previously receive an allogeneic HSCT? ○ Yes ○ No

c. Performance Status
- ○ Karnofsky Performance Status (for patients 16 years old and older)
- ○ Lansky Performance Status (for patients under 16 years old)

○ 50 ○ 60 ○ 70 ○ 80 ○ 90 ○ 100

d. Has the patient previously received CAR T-cell therapy? ○ Yes ○ No

If yes, specify product: .....

## 4. Funded Dose

Cycle 1:
Blinatumomab 5 mcg/$m^2$/day for days 1-7, followed by blinatumomab 15 mcg/$m^2$/day for 21 days, followed by a 14-day treatment-free interval

Subsequent cycles (up to a maximum of 5 total cycles):
Blinatumomab 15 mcg/$m^2$/day for 28 days, followed by a 14-day treatment-free interval

Patients achieving a complete response (CR) within the first two treatment cycles could receive up to three additional cycles of blinatumomab (5 cycles maximum).

## 5. Notes

1. 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.
3. Patients who completed 4 cycles of blinatumomab for minimal residual disease-positive BCP-ALL are not eligible for blinatumomab retreatment.

## 6. FAQs

i. **My patient is currently receiving blinatumomab 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 blinatumomab through the New Drug Funding Program.

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

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. **Is blinatumomab funded for first relapse (i.e., only had one prior line of therapy)?**

The current NDFP funding for blinatumomab in the pediatric population is specific for patients with relapsed/refractory disease as defined in the pivotal trial. Specifically, blinatumomab is funded for patients who have had a second or later bone marrow relapse, or any marrow relapse after an allogeneic HSCT. Refractory disease is defined as patients who have not achieved a first remission and have failed a full standard induction regimen, or patients in first relapse who have failed to achieve a complete remission following full standard reinduction chemotherapy of at least four weeks in duration.

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

For some sites with an integrated Computerized Prescriber Order Entry (CPOE) system 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 application. 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."

v. **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 and will appear separately 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.

## 7. Supporting Documents

None required for this policy.

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

- Clinic notes confirming the patient’s diagnosis, relapsed/refractory disease, and protocol.

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

..... ..... .....
Day Month Year

*Form 898*