Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

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

This is a renamed version of *Blinatumomab - Relapsed or Refractory Acute Lymphoblastic Leukemia* policy.

(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:

- Adult patients with Philadelphia chromosome-negative (Ph-) relapsed or refractory B precursor acute lymphoblastic leukemia (ALL). Treatment should be for patients with a good performance status. ☐ Yes

3. Baseline Information

a. ECOG performance status at the time of enrolment ○ 0 ○ 1 ○ 2

b. Blinatumomab is being used for: ○ Primary refractory ○ 1st relapse ○ 2nd relapse ○ 3rd relapse ○ 4th or subsequent relapse

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).

5. Notes

1. 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.
3. NDFP will provide funding for 2 cycles of induction and 3 cycles of consolidation. Maintenance blinatumomab is not funded by NDFP.
4. For patients currently enrolled on the third line blinatumomab policy, treatments can continue to be submitted on the existing policy. Please note, however, that the existing policy will be archived and no longer available for new patient enrolments.
5. 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 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 sequencing of blinatumomab and inotuzumab ozogamicin allowed?**

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 take the patient to transplant if response can be achieved.

vi. **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.

7. Supporting Documents

None required for this policy.

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

- Clinic note documenting previous treatment history

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

....
Day Month Year

Form 897