



Blinatumomab - Front-line Consolidation for 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 (m²): * 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

Blinatumomab will be used for the treatment of adult and pediatric patients with Philadelphia chromosome-negative (Ph-negative), CD19-positive B-cell precursor acute lymphoblastic leukemia (B-ALL) who are in the consolidation phase of multiphase chemotherapy in the front-line setting. Yes

Patients must be in complete remission (CR) or CR with incomplete count recovery (CRi) after induction chemotherapy.

3. Baseline Information

- a. Please select the blinatumomab dosing protocol Pediatric Adult
- b. ECOG Performance Status at the time of enrolment 0 1 2
- c. Karnofsky (for patients 16 years old and older) or Lansky (for patients under 16 years old) PS for pediatric patients 50 60 70 80
 90 100
- d. Minimal Residual Disease (MRD) status Positive Negative
- e. Is the patient transitioning from a private pay or compassionate program? Yes No
- f. If yes, please enter the number of days of blinatumomab the patient has received. _____

4. Funded Dose

Pediatric patients:

Blinatumomab 15 mcg/m²/day for 28 days continuously, followed by a 7-day treatment-free interval, up to a maximum of 2 cycles.

Adult patients:

Blinatumomab 28 mcg/day for 28 days continuously, followed by a 14-day treatment-free interval, up to a maximum of 4 cycles.

Treatment should continue until disease progression or unacceptable toxicity up to the maximum number of cycles stipulated above, whichever comes first.

[ST-QBP regimen code(s): BLIN]

5. Notes

1. Patients with Philadelphia chromosome-positive B-ALL, acute undifferentiated leukemia, or Burkitt leukemia are not eligible for blinatumomab funding under this policy.
2. NDFP will provide coverage of blinatumomab in both the inpatient and outpatient settings, provided that funding criteria are met.
3. 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 “overflow” 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 “overflow” amount will be automatically captured in eClaims according to the treatment doses submitted.

6. FAQs

1. **My patient is currently receiving blinatumomab through non-publicly funded means (e.g., patient support program, private insurance). Can my patient be transitioned to receive funding through 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 continued coverage through the NDFP.

2. **What is the process for transitioning my patient from a non-publicly funded program to NDFP funding?**

If your patient meets all of the eligibility criteria outlined in this policy, please submit as a regular eClaims enrolment.

Prior approval requests are reserved for instances where there is clinical uncertainty on eligibility. In these circumstances, please specify your reason(s) for uncertainty and upload the following:

- Pathology report confirming Ph-negative, CD19-positive B-ALL
- Clinic notes and/or pathology reports confirming CR or CRi status.

Please note: Patients who meet the NDFP eligibility criteria and are enrolled in the manufacturer’s patient support program (PSP) are eligible to receive continued drug supply through the PSP until March 28, 2026, inclusive.

After this date, patients who met the NDFP eligibility criteria at the point of treatment initiation are eligible to transition to NDFP funding for the remainder of their treatment course. Although sites may enroll their patient onto this policy at any time beforehand, any treatment claims submitted to eClaims that were given on or before the PSP transition date will be denied.

Supporting Documents

None required at time of enrolment.

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

- Pathology report confirming Ph-negative, CD19-positive B-ALL
- Clinic notes and/or pathology reports confirming CR or CRi status.

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

.....
Day Month Year

Form 1118