Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

# Inotuzumab Ozogamicin (Outpatient) - Relapsed or Refractory Acute Lymphoblastic Leukemia

This is a renamed version of Inotuzumab Ozogamicin - Relapsed or Refractory 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 * 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

The patient must meet the following criteria:

- For the treatment of Philadelphia chromosome (Ph)-positive and Ph-negative patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) who have good performance status. ☐ Yes
- [For patients with Ph-positive ALL, failure with at least one second-generation or third-generation tyrosine kinase inhibitor (TKI) and standard multi-drug induction chemotherapy is required before treatment with inotuzumab ozogamicin.]

## 3. Baseline Information

a. Does this patient have an enrolment for the inpatient version of this policy? ○ Yes ○ No

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

c. Line of salvage treatment:
○ First
○ Second and beyond

d. Philadelphia chromosome status: ○ Negative ○ Positive

e. If Ph-positive, please select the second and/or third-generation tyrosine kinase inihibitor(s) used:
☐ Dasatinib ☐ Ponatinib
☐ Other

If 'other', please specify: .....

f. If Ph-positive, please indicate the standard multi-drug chemotherapy used as part of induction:
☐ Dana Farber ☐ HyperCVAD
☐ Other

If 'other', please specify: .....

## 4. Funded Dose

**Cycle 1:**
Inotuzumab ozogamicin 0.8 mg/$m^2$ intravenously (IV) on day 1 followed by inotuzumab ozogamicin 0.5 mg/$m^2$ IV on days 8 and 15 [total dose per cycle = 1.8 mg/$m^2$].
Cycle 1 is 21 days [ST-QBP regimen code: INOT].

**Subsequent cycles:**
For patients who achieve a complete response or complete response with incomplete count recovery (CR/CRi): Inotuzumab ozogamicin 0.5 mg/$m^2$ IV on days 1, 8 and 15 [total dose per cycle = 1.5 mg/$m^2$].
For patients who have not achieved a CR/CRi: Inotuzumab ozogamicin 0.8 mg/$m^2$ IV on day 1 followed by 0.5 mg/$m^2$ IV on days 8 and 15 [total dose per cycle = 1.8 mg/$m^2$].
Subsequent cycles are 28 days [ST-QBP regimen code: INOT].

Treatment should be continued until unacceptable toxicity or disease progression, up to a maximum of three cycles, for those patients proceeding to hematopoietic stem cell transplant (HSCT).

For patients not proceeding to HSCT who achieve CR/CRi and minimal residual disease (MRD) negativity, treatment may be continued for a maximum of six total cycles.

## 5. Notes

1. Enrolment in this policy is for funding of inotuzumab ozogamicin doses administered in the outpatient setting only.

   Please ensure all claims are submitted through eClaims under the appropriate policies for inpatient and outpatient use.

2. For funding of doses administered in the inpatient setting, a separate enrolment form must be submitted. Refer to the High Cost Therapy Funding Program (HCTFP) policy entitled ‘Inotuzumab Ozogamicin (Inpatient) - Relapsed or Refractory Acute Lymphoblastic Leukemia'.

## 6. FAQs

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

   Provided all other eligibility criteria are met, the NDFP and HCTFP can fund sequencing of both blinatumomab and inotuzumab ozogamicin in curative situations for relapsed Ph-positive and Ph-negative ALL. This will be defined as a goal to take the patient to transplant if response can be achieved.

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

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

3. ***My patient has an overt relapse of Ph-positive ALL after first line induction (chemotherapy + TKI). Would they be eligible for inotuzumab ozogamicin?***

   The NDFP may consider patients with overt relapse of Ph-positive 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 inotuzumab ozogamicin in eClaims along with relevant documentation for review.

4. ***Is confirmation of MRD negativity a requirement for ongoing funding of inotuzumab ozogamicin?***

   In order to be eligible for 6 total cycles of inotuzumab ozogamicin, sites are required to upload a pathology report demonstrating MRD negativity. As referenced in the Health Canada Product Monograph, 'if CR or CRi and MRD negativity is not achieved by cycle 3, treatment should be permanently discontinued.'

   In consultation with clinical experts, MRD testing for Ph-positive ALL patients should be considered standard of care whereas MRD testing for Ph-negative ALL is not yet standardized and continues to evolve.

5. ***How will treatment claims be managed in eClaims?***

   Only outpatient treatment claims should be submitted under this policy. Doses administered in the outpatient setting are submitted as per the site's usual procedure. Inpatient administered doses must be submitted under the policy 'Inotuzumab Ozogamicin (Inpatient) – Relapsed or Refractory Acute Lymphoblastic Leukemia'.

## 7. Supporting Documents

For continuation of inotuzumab ozogamicin beyond 3 cycles, please upload a pathology report demonstrating MRD negativity.

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

- Clinic notes documenting treatment history

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

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