Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Crisantaspase Recombinant - Acute Lymphoblastic Leukemia, Lymphoblastic Lymphoma, Mixed or Biphenotypic 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 (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

Crisantaspase recombinant is used for the treatment of pediatric and adult patients with acute lymphoblastic leukemia, lymphoblastic lymphoma, or mixed/biphenotypic leukemia with a documented hypersensitivity reaction or silent inactivation to an *Escherichia coli (E.coli)*-derived asparaginase.

☐ Yes

3. Baseline Information

a. Indication for crisantaspase recombinant

○ Hypersensitivity reaction
○ Silent inactivation

b. Treatment Setting

○ Previously untreated
○ Relapsed or refractory

4. Funded Dose

Crisantaspase recombinant intramuscularly (IM) three times per week (25 mg/m^2 on Monday and Wednesday, then 50 mg/m^2 on Friday) for a total of 6 doses to replace each planned dose of pegaspargase.

Treatment should be discontinued in patients who experience a hypersensitivity reaction, silent inactivation, high grade toxicities, or evidence of disease progression.

5. Notes

1. Patients with a history of a hypersensitivity reaction to an E. coli-derived asparaginase should have experienced a grade 3 (or higher) allergic reaction as per the Common Terminology Criteria for Adverse Events (version 5.0).

2. There is a risk of medication errors between the available asparaginase products. Please note that crisantaspase recombinant is dosed using milligrams per meter squared and not by units per meter squared.

3. Patients should not be treated with crisantaspase recombinant if they have a history of grade 3 or higher pancreatitis (per the Common Terminology Criteria for Adverse Events, version 5.0).

4. In the literature, a nadir serum asparaginase activity (NSAA) level of greater than or equal to 0.1 IU/mL was considered to be the minimum threshold for adequate asparaginase activity.

5. Crisantaspase recombinant will be reimbursed on a per vial basis.

6. FAQs

1. **Will patients with relapsed or refractory acute lymphoblastic leukemia, lymphoblastic lymphoma, or mixed/biphenotypic leukemia be eligible for funding?**

   Both newly diagnosed and relapsed or refractory acute lymphoblastic leukemia, lymphoblastic lymphoma, or mixed/biphenotypic leukemia patients will be eligible for crisantaspase recombinant funding under this policy provided all the eligibility criteria are met. Please submit a new enrolment if use is required in the relapsed or refractory setting.

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:

- Clinic note(s) describing the hypersensitivity reaction (of grade 3 or higher) or silent inactivation to an E. coli-derived asparaginase; AND
- If able to assess, the NSAA therapeutic drug monitoring levels

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

....
Day Month Year

Form 1035