

# Erwinia Asparaginase - Relapsed or Refractory Pediatric Acute Lymphoblastic Leukemia, Lymphoblastic Lymphoma, or Mixed/Biphenotypic 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<sup>2</sup>): ..... \* 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)
- .....

**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:

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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:

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## 2. Eligibility Criteria

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The patient must meet the following criteria:

- Erwinia asparaginase is used in the treatment of relapsed or refractory pediatric<sup>1,2</sup> acute lymphoblastic leukemia, lymphoblastic lymphoma or mixed/biphenotypic leukemia.  Yes

1. The patient is eligible for Erwinia asparaginase if the diagnosis occurred prior to 18 years of age.

2. If the diagnosis occurred at 18 or 19 years of age, the patient is eligible for CCO funding if Erwinia asparaginase is administered at a POGO-affiliated pediatric cancer centre or satellite site and the patient's care is managed by a pediatric oncology service.

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## 3. Baseline Information

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- a. Protocol (\*or Standard of Care protocol equivalent):  
Note: Patients are eligible for CCO funding of Erwinia asparaginase if used as part of the standard of care backbone of the COG clinical trial.

- UK ALL R3\*  
 AALL1331\*  
 Other

Other (specify): \_\_\_\_\_

- b. There is documented clinical or laboratory detected allergy to pegaspargase.  Yes  No

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## 4. Funded Dose

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Erwinia asparaginase up to 25,000U/m<sup>2</sup>/dose IV or IM

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## 5. Notes

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1. Erwinia asparaginase will be reimbursed on a per vial basis.

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## 6. Supporting Documents

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None required.

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

- If applicable, a clinic note confirming the allergy or silent inactivation to pegaspargase.

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

.....  
Day    Month    Year