Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Epcoritamab (Outpatient) - Relapsed or Refractory Diffuse Large B-Cell Lymphoma

(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 (comple 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

Epcoritamab will be used in the following adult patients with relapsed or refractory disease: ☐ Yes

- Diffuse Large B-Cell Lymphoma (DLBCL), not otherwise specified (NOS); OR
- DLBCL transformed from an indolent lymphoma; OR
- High grade B-Cell Lymphoma (HGBCL); OR
- Primary Mediastinal B-Cell Lymphoma (PMBCL); OR
- Follicular Lymphoma grade 3b (FLG3b)/ Follicular Large B-Cell Lymphoma (FLBCL).

Patients must be previously treated with two or more lines of systemic therapy and have previously received, or are unable to receive, chimeric antigen receptor (CAR) T-cell therapy.

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. Patient's diagnosis: ○ DLBCL NOS ○ Transformed DLBCL ○ HGBCL ○ PMBCL ○ FLG3b/FLBCL

d. Current LDH value: ○ Elevated ○ Normal

e. Number of extranodal sites just prior to starting epcoritamab: ○ 0 ○ 1 ○ Greater than 1

f. Current location(s) of extranodal disease (select all that apply): ☐ Adrenal ☐ Kidney ☐ Bone Marrow ☐ Testicular ☐ Bone ☐ Other_____

If other, please specify the location(s) .....

g. Current lymphoma stage: ○ I ○ II ○ III ○ IV

h. Is the patient transitioning from a private payer or compassionate program? ○ Yes ○ No

i. If yes, please indicate the date of the last administered dose. ..... _____ ..... Day Month Year

4. Funded Dose

Cycle 1:
Epcoritamab 0.16 mg (priming dose) subcutaneously (SC) on day 1, then 0.8 mg (intermediate dose) SC on day 8, then 48 mg (full dose) on days 15 and 22

Cycle 2 and 3:
Epcoritamab 48 mg SC on days 1, 8, 15, and 22

Cycles 4 to 9:
Epcoritamab 48 mg SC on days 1 and 15

Cycles 10 and onwards:
Epcoritamab 48 mg SC on day 1

Treatment should continue until disease progression or unacceptable toxicity, whichever comes first.

1 cycle = 28 days

[ST-QBP regimen code(s): EPCO(RAMP) for cycle 1, EPCO]

5. Notes

1. Enrolment in this policy is for funding of epcoritamab doses administered in the outpatient setting only. For the funding of doses administered in the inpatient setting, a separate enrolment form must be submitted. See the policy Epcoritamab (Inpatient) - Relapsed or Refractory Diffuse Large B-Cell Lymphoma.

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

2. Epcoritamab will be reimbursed on a per vial basis.

3. Patients will be ineligible for epcoritamab if they have central nervous system (CNS) lymphoma or CNS involvement, or had a prior allogeneic stem cell transplant or solid organ transplant.

4. Patients with relapsed or refractory DLBCL are eligible for one bispecific T-cell engager therapy (e.g.glofitamab, epcoritamab) if all funding criteria are met.

6. FAQs

1. **My patient is currently receiving epcoritamab 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:
   - A clinic note and imaging (if applicable) from treatment initiation, and
   - The most recent clinic note and imaging (if applicable).

   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 January 18, 2025, 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.

7. 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 notes outlining patient and treatment history/response.
- CT scans demonstrating no disease progression.

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

Day Month Year