Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Glofitamab (Outpatient) - Relapsed or Refractory Diffuse Large B-cell Lymphoma

(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)

.....

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

Glofitamab will be used for the treatment of adult patients with relapsed or refractory aggressive histology lymphoma with the following subtypes: ☐ 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 have received 2 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. Is the patient transitioning from a private payer or compassionate program? ○ Yes ○ No

e. If yes, please indicate the funding source ○ Private payer ○ Manufacturer patient support program

f. If yes, how many cycles of glofitamab did the patient receive prior to the transition? ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○ 11

g. Current LDH value: ○ Elevated ○ Normal

h. Number of extranodal sites at the time of glofitamab initiation: ○ 0 ○ 1 ○ 2 ○ Greater than 2

i. Current locations(s) of extranodal disease (select all that apply): ○ Adrenal ○ Kidney ○ Bone Marrow ○ Testicular ○ Bone ○ Other

If other, please specify the location(s) _____

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

4. Funded Dose

Cycle 1:
Day 1 – Obinutuzumab 1000 mg intravenously (IV)
Day 8 – Glofitamab 2.5 mg IV
Day 15 – Glofitamab 10 mg IV

Cycles 2 to 12:
Glofitamab 30 mg IV on day 1 only

Treatment should continue until disease progression or unacceptable toxicity, up to a maximum of 12 cycles, whichever comes first.

1 cycle = 21 days

If a treatment-free interval of 6 weeks or more occurs after cycle 1, repeat cycle 1 dosing before resuming the planned treatment cycle (30 mg IV every 21 days).

[ST-QBP regimen code(s): GLOF(RAMP) for cycles 1 and 2, GLOF for cycles 3 to 12]

5. Notes

1. Enrolment in this policy is for funding of glofitamab 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 Glofitamab (Inpatient) – Relapsed or Refractory Diffuse Large B-Cell Lymphoma.

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

2. Completion of this form will satisfy funding requirements for both obinutuzumab and glofitamab.

3. Patients with current or past history of central nervous system (CNS) lymphoma, chronic lymphocytic leukemia (CLL), Burkitt lymphoma, lymphoplasmacytic lymphoma, or prior solid organ transplant are not eligible for glofitamab funding.

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.

5. Patients who complete the initial course of glofitamab may be eligible for one course of retreatment (until disease progression or unacceptable toxicity, up to a maximum of 12 cycles) if the patient achieves a disease-free interval of at least 6 months after completing the initial course of glofitamab. Claims should be submitted under the same forms used for the initial course of therapy.

6. FAQs

1. **My patient is currently receiving glofitamab 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.

   Funding for glofitamab is up to a maximum of 12 cycles for initial therapy and one course of retreatment (if applicable), regardless of funding source.

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 22, 2025, inclusive.

   For patients enrolled in the PSP and receiving the PSP-supplied drug in a private infusion clinic, these patients can be transitioned to the hospital or cancer centre and continue to receive PSP-supplied drug until January 22, 2025. The hospital or cancer centre should coordinate the supply of PSP-supplied drug between the PSP and their respective sites, if not done so already.

   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.

3. **My patient was treated with an alternate bispecific T-cell engager therapy and has experienced disease progression. Can I treat them with glofitamab?**

   Patients who experience disease progression after completing treatment with an alternate bispecific T-cell engager therapy (e.g. epcoritamab) for relapsed or refractory DLBCL will not be eligible for glofitamab funding.

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 .....

Form 1064