Ontario Health
Cancer Care Ontario

Enrolment Form

CAR T-cell Therapy for Relapsed/Refractory Lymphoma (Third or Subsequent Line)

This form should be completed before apheresis to confirm patient eligibility.

Completed form and supporting documentation should be submitted through the online portal: https://mft.cancercare.on.ca.
Username: CARTSubmission
Password: Contact our program at **OH-CCO_CARTSubmissions@ontariohealth.ca**

Ontario Health collects and uses information on this form in order to determine if the patient meets the eligibility and funding criteria for the CAR T-cell Therapy Program, resulting in reimbursement to the treating facility. They also collect and use information on this form for purposes of analysis or compiling statistical information with respect to the management of, evaluation or monitoring of, the allocation of resources to or planning for all or part of the health system, including the delivery of services, pursuant to Section 45 of the Personal Health Information Protection Act, 2004.

As part of the evaluation of the request, it may be necessary for Ontario Health to disclose the patient's personal health information (PHI) to other administrative programs for health services and insured benefits at the Ministry of Health.

*Required Fields

1. Patient Profile

*Surname: _____

*Given Name: _____

*Date of Birth: MM/DD/YYYY *(MM/DD/YYYY - Click arrow down button to use calendar to enter the date)*

*Gender: ◯ Male ◯ Female ◯ Other Height (cm): _____ Weight (kg): _____

*Province/Territory of Patient Residence: ◯ AB ◯ BC ◯ MB ◯ NB ◯ NL ◯ NT ◯ NS ◯ NU ◯ ON ◯ PE ◯ QC ◯ SK ◯ YT

*Postal Code of Patient Residence: A1A 1A1

*Provincial/Territorial Health Card Number: _____

Note: If your patient is not a resident of Ontario, a funding approval letter from the patient's provincial/territorial Ministry of Health is required.

2. Enroling Site

*Province/Territory of Enroling Site: ◯ AB ◯ BC ◯ MB ◯ NB ◯ NL ◯ NT ◯ NS ◯ NU ◯ ON ◯ PE ◯ QC ◯ SK ◯ YT

*Enroling Site: _____

*Patient Chart Number (MRN) at Enroling Site: _____

*Enroling Physician: Given Name Surname

Enroling Physician CPSO Number (Ontario Only): _____

*Enroling Physician Speciality: _____

*Enroling Physician Email: _____

*Enroling Physician Cell Phone Number: XXX-XXX-XXXX

*Enroling Physician Fax Number: XXX-XXX-XXXX

Alternate Contact Email: _____

Note: If an alternate contact email is provided, the alternate contact will be copied on all email correspondence about this enrolment.

3. Treatment Centre and Product Information

Before submitting this form, confirm the CAR T-cell Therapy Centre has capacity and has agreed to treat your patient. Email or fax confirmation is required when submitting this enrolment package. CAR T-cell Therapy Centre contact details are available at https://www.cancercareontario.ca/en/find-cancer-services/car-t-cell-therapy-centres

If your patient will be treated out-of-country, please also complete section 8.

*Will this patient receive CAR T-cell therapy in Ontario? ◯ Yes ◯ No

If patient will be treated **in Ontario**, select CAR T-cell therapy site:
- ◯ Juravinski Cancer Centre - Hamilton Health Sciences
- ◯ Princess Margaret Cancer Centre - University Health Network
- ◯ The Ottawa Hospital

If patient will be treated **in another province** in Canada, please provide CAR T-cell therapy site and location: _____

If patient will be treated **out of country**, please indicate the treating facility:
- ◯ Roswell Park Comprehensive Cancer Center (Buffalo, New York)
- ◯ Cleveland Clinic (Cleveland, Ohio)
- ◯ Karmanos Cancer Institute (Detroit, Michigan)

*Treating Physician at CAR T-cell therapy site: Given Name Surname

*Requested CAR T-cell therapy product:
- ◯ Kymriah (tisagenlecleucel)
- ◯ Yescarta (axicabtagene ciloleucel)

Note: Switching CAR T-cell products will require replacement of the original funding letter that was issued. Contact the program immediately in case there is a need to use another product.

Anticipated date of treatment (MM/DD/YYYY): MM/DD/YYYY *(Click arrow down button to use calendar to enter the date)*

4. Funding Criteria

***A. The patient must meet the following criteria:** ☐ I confirm that my patient meets the funding criteria outlined below:

- Patient has relapsed[1] or refractory[2] large B-cell lymphoma after two or more lines of systemic therapy
- Patient does not have active CNS disease[3]
- Patient is sufficiently stable to facilitate planned CAR T-cell therapy (e.g., not rapidly progressing on temporizing therapy, no significant compromise of vital organ functions, no need for intubation or dialysis, and does not require ICU/pressors) and has good performance status
- Patient has not previously received an adoptive T-cell immunotherapy
- Patient has not previously received an allogeneic stem cell transplant
- Patient has not previously received an anti-CD19 therapy (e.g., blinatumomab, tafasitamab)

***B. Patient has the following diagnosis[4]:**
- ◯ Diffuse large B-cell lymphoma (DLBCL) not otherwise specified
- ◯ High grade B-cell lymphoma
- ◯ High grade B-cell lymphoma with MYC and BCL2 and/or BCL6 rearrangements (double hit by FISH)
- ◯ DLBCL arising from follicular lymphoma
- ◯ Primary mediastinal large B-cell lymphoma (PMBCL)

Note: As evidence and clinical practice evolve, eligibility criteria is subject to change. Additional notes are provided on page 3.

[1]Relapsed disease: indicates a partial or complete response to the last line of therapy and subsequent progression before enrolment.

[2]Refractory disease: indicates progressive or stable disease as the best response to the last therapy before enrolment or response status unknown.

[3]For CNS lymphomas, active CNS disease is defined as recent neurologic sign/symptoms, and/or positive imaging studies (MRI, PET scan) and/or positive cerebrospinal fluid (CSF) study. Primary CNS lymphoma is currently not eligible for funding while treated and inactive secondary CNS lymphoma may be eligible for funding.

[4]Diagnoses not specifically included in the Health Canada approved product monographs are not eligible for consideration.

5. Treatment History

*A. How many lines of systemic therapy has the patient previously received? ◯ 2 ◯ 3 or More

6. Confirmation of Patient Suitability for Therapy

*A. Patient has acute life threatening bacterial, viral (HIV, active hepatitis B or C) or fungal infection or an inflammatory disorder:
◯ No Infection
◯ Controlled Infection
◯ Uncontrolled Infection

*B. Karnofsky Performance Status (KPS) ≤70%: ◯ Yes ◯ No

Renal Function:

*C. Creatinine ≥141.44 µmol/L (1.6 mg/dL): ◯ Yes ◯ No

*D. Estimated glomerular filtration rate (eGFR) ≤45 ml/min/1.73m^2: ◯ Yes ◯ No

Liver Function:

*E. ALT or AST ≥3x upper limit of normal value: ◯ Yes ◯ No

*F. Bilirubin ≥2x upper limit of normal value: ◯ Yes ◯ No

Pulmonary Function:

*G. Pulse oxygenation ≤91% on room air: ◯ Yes ◯ No

Cardiac Function:

*H. Left ventriclular ejection fraction (LVEF) ≤40% confirmed by echocardiogram or Multigated Radionuclide Angiography (MUGA): ◯ Yes ◯ No

Bone Marrow Function:

*I. Absolute neutrophil count (ANC) ≤1.0x10^9/L (1000/mm^3): ◯ Yes ◯ No

*J. Absolute lymphocyte count (ALC) <0.1x10^9/L (100/mm^3): ◯ Yes ◯ No

Note: If ALC is below 0.1x10^9/L, application can be considered; but for apheresis to proceed, ALC must be at least 0.1x10^9/L.

*K. Hemoglobin ≤80 g/L (8.0 g/dL) and/or transfusion dependent: ◯ Yes ◯ No

*L. Platelets ≤50x10^9/L (50,000/mm^3): ◯ Yes ◯ No

7. Additional Notes

a. Treatment with either tisagenlecleucel or axicabtagene ciloleucel is a one-time therapy.
b. Tisagenlecleucel or axicabtagene ciloleucel should not be used in combination with other treatments for relapsed/refractory lymphoma.
c. At least six weeks must have elapsed from any prior systemic inhibitory/stimulatory immune checkpoint molecule therapy (e.g., nivolumab, pembrolizumab, etc.) to the time of CAR T-cell product infusion.
d. A patient with another malignancy must be in complete remission with said malignancy prior to receiving CAR T-cell therapy.
e. Patients who have had an autologous stem cell transplant in the last 100 days must meet funding criteria at the time of enrolment.
f. Patients must meet the funding criteria at the time of enrolment and must continue to be eligible and suitable for therapy at the time of product infusion.

8. Out-of-Country Applications - Additional Requirements

Only complete this section if you are an Ontario physician applying for an Ontario patient to be treated out-of-country:

1. Submit all the documents listed under "Supporting Documents" in section 8.
2. Download, complete and submit the Ministry form “Request for Prior Approval for Full Payment of Insured Out-of-Country (OOC) Health Services”.

- The form can be found in the Central Forms Repository at: http://www.forms.ssb.gov.on.ca/mbs/ssb/forms/ssbforms.nsf/FormDetail?OpenForm&ACT=RDR&TAB=PROFILE&SRCH=&ENV=WWE&TIT=4520&NO=014-4520-84
- Complete as indicated below:
  - Section 1: patient name, mailing address and phone number only
  - Section 2: physician name and office address only
  - Section 3: all fields
  - Section 5: all fields up to but not including anything after “If treatment is not available in Ontario”
  - Sections not required: section 4, 6, and patient/physician signatures

9. Non-Ontario Enroling Physicians - Additional Requirements

If this application is from a non-Ontario physician, please complete this section.

Consent ☐ Yes

By checking this box, I confirm that the patient named above, or relevant substitute decision-maker where applicable, consents that the patient's personal health information (PHI) will be collected and used by Ontario Health, in order to determine if the patient meets the eligibility and funding criteria for the CAR T-cell Therapy Program, resulting in reimbursement to the treating facility. Ontario Health also collects and uses information on this form for purposes of analysis or compiling statistical information with respect to the management of, evaluation or monitoring of, the allocation of resources to or planning for all or part of the health system, including the delivery of services. As part of the evaluation of the request, it may be necessary for Ontario Health to disclose the patient's PHI to other administrative programs for health services and insured benefits at the Ministry of Health.

10. Supporting Documents

If the enrolment is for an Out-of-Country treatment for an Ontario patient, the following documentation (from **Lists A and B**) **must be** submitted with the enrolment form. The Ministry form "Request for Prior Approval for Full Payment of Insured Out-of-Country (OOC) Health Services" must also be included in the enrolment package.

If the enrolment is for in-Ontario treatment, the documents under **List A must be** submitted and documents under **List B** should be available upon request (including for the purpose of audit) to confirm eligibility.

***List A: Required upon enrolment**

- ☐ If any of the answers to section 6 are "Yes", submit relevant & recent laboratory results showing adequate organ function (e.g., kidney and liver function tests, viral serology, cardiac ECHO/MUGA)
- ☐ Pathology report
- ☐ Email or fax from the treating facility confirming they will treat this patient
- ☐ If the request is for treatment out-of-country, email or fax from the Ontario treating facilities confirming no capacity
- ☐ If the request is for a non-Ontario resident, a funding approval letter from the patient's provincial/territorial Ministry of Health is required, specifying CAR T-cell product(s) that is/are funded by the patient's provincial/territorial Ministry of Health

List B: Available upon request

- ☐ Recent clinical notes reflecting clinical situation and status of patient (last three clinic visits)
- ☐ Bone Marrow (BM) studies including most recent studies
- ☐ Cerebrospinal Fluid (CSF) studies documenting CNS remission status (within the last 30 days)
- ☐ Documentation of CD19 tumour expression in BM or peripheral blood by flow cytometry (if done)
- ☐ Pre and post-treatment imaging reports e.g., CT scan (post-treatment imaging reports must be within the last 30 days)
- ☐ Multidisciplinary case conference (MCC)/tumour board notes (if available)

*By checking this box, I certify that the information set out in this questionnaire is true and accurate, to the best of my knowledge: ☐ Yes

*Enroling Physician: Given Name Surname *Date (MM/DD/YYYY): MM/DD/YYYY *(Click arrow down button to use calendar to enter the date)*

Need this information in an accessible format? 1-877-280-8538, TTY 1-800-855-0511, info@ontariohealth.ca