



Chimeric Antigen Receptor (CAR) T-cell Therapy

Clinical Trials Funding Policy

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Ontario Health
Cancer Care Ontario

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CAR T-Cell Therapy Clinical Trials Funding Policy

Introduction

Chimeric antigen receptor (CAR) T-cell therapy is a type of immune effector cell (IEC) therapy that harnesses a person's own immune cells to fight cancer. Since 2019, Cancer Care Ontario (now a part of Ontario Health) has provided oversight for the delivery of CAR T-cell therapy in Ontario through the Ontario CAR T-cell Therapy Program, including monitoring access, performance and quality outcomes, capacity planning and funding the delivery of commercially available CAR T-cell therapy products.

Since the launch of the Ontario CAR T-cell Therapy Program, the number of patients treated with CAR T-cell therapy has grown year-over-year. With the high cost of commercial CAR T-cell products, growth in this therapy's utilization has come with significant budget implications. With many new CAR T-cell products in the pipeline for an increasing number of indications, the total cost of this therapy will continue to grow, and sustainable solutions are needed.

As of 2024, Ontario Health (Cancer Care Ontario) will be providing funding to support CAR T-cell therapy clinical trials in Ontario to:

- increase access to care,
- drive Canadian innovation and advancement in technology, and
- potentially improve the long-term financial sustainability of therapies.

This funding will provide coverage for the costs associated with the standard of clinical care for eligible academic CAR T-cell therapy clinical trials. Funding will not support the costs of clinical trial activity or the development or manufacturing of CAR T-cell therapy products. Funding will not support industry/for-profit entity-led or sponsored clinical trials.

Purpose

The purpose of the CAR T-cell Therapy Funding Policy (this *Policy*) is to:

- 1) Detail eligibility criteria which a Clinical Trial must meet to receive funding;
- 2) Describe the Application process which an Applicant must follow to apply for funding; and
- 3) Guide Ontario Health (Cancer Care Ontario)'s assessment and evaluation of Applications against set eligibility criteria.

Public Funding of CAR T-cell Therapy

Ontario has an established process for evaluating CAR T-cell products for public funding^{1,2}. CAR T-cell therapy products and clinical care costs associated with the delivery of the therapy and follow-up care are funded by the Ontario Health (Cancer Care Ontario) CAR T-cell Therapy Program. Funding rates are subject to change over time.

It is important to note that the CAR T-cell Therapy Program does not directly fund clinical trials.

Definitions

Applicant: A Principal Investigator of a CAR T-cell therapy clinical trial in Ontario.

Application: A completed CAR T-cell Therapy Clinical Trial Application Form with required supporting documentation.

Clinical trial: A type of clinical study in which participants are assigned to groups that receive one or more intervention(s)/treatment(s) (or no intervention) so that researchers can evaluate the effects of the intervention(s) on biomedical or health-related outcomes. The assignments are determined by the study's protocol. Participants may receive diagnostic, therapeutic, or other types of interventions³.

Ontario residents: Residents of Ontario who have a valid Ontario Health Card Number.

Reconsideration: The Applicant may request a reconsideration of an initial Application or a resubmission request with a negative assessment (i.e., not aligned with criteria), if the Applicant believes the eligibility criteria were wrongfully applied to the Application in the absence of new pertinent information that may change the assessment.

Resubmission: The Applicant may request a resubmission of an initial Application with a negative assessment (i.e., not aligned with criteria), if the Applicant has new evidence or pertinent information that may change the assessment.

Scope

This *Policy* will describe the framework, criteria, and process by which a Principal Investigator may submit a CAR T-cell therapy clinical trial to be assessed to receive funding of costs associated with the standard of clinical care for eligible academic CAR T-cell therapy clinical trials, in alignment with current Ontario CAR T-cell Therapy Program funding rates. It will also provide clarity and transparency

¹ <https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/hematologic/car-t-cell-therapy-enrolment>

² Implementation of a CAR T-cell therapy product public funding in Ontario is dependent on 1) Health Canada issuing a Notice of Compliance, 2) positive funding recommendation from the Canadian Agency for Drugs and Technologies in Health (CADTH), 3) successful completion of national price negotiations, and 4) decision from the Ministry of Health to fund the product.

³ Clinicaltrials.gov. (2020). Clinical trial. Glossary of common site terms. Available at <https://clinicaltrials.gov/ct2/about-studies/glossary>

as to how participation in a clinical trial may potentially impact the patient’s eligibility for public funding. Funding for clinical trial costs and products is outside the scope of this policy.

This *Policy* is specific to academic CAR T-cell therapy clinical trials assessing the clinical benefit of investigational CAR T-cell therapy products. Clinical trials assessing investigational oncology drugs, should refer to the [Systemic Treatment Clinical Trials Policy](#).

Eligibility Criteria

The following eligibility criteria and considerations will be used to evaluate whether a CAR T-cell therapy clinical trial is eligible for funding of costs associated with the standard of clinical care in Ontario.

In order to be eligible for funding through this *Policy*, the clinical trial must meet the following criteria:

- The clinical trial must have an established funding source for CAR T-cell product costs and the clinical trial administration/operational costs.
- The clinical trial must be funded by a Canadian academic institution. Industry/for-profit entity-led or sponsored clinical trials are not eligible.
- The clinical trial must be evaluating the clinical benefit of an investigational Canadian-developed CAR T-cell therapy product for humans.
- The clinical trial must be oncology specific.
- The clinical trial must be operated at a FACT (Foundation for the Accreditation of Cellular Therapy) accredited hospital(s)/cancer centre(s) in Ontario, Canada.
- The clinical trial must receive research ethics board approval prior to the administration of funding.

Considerations

- Funding provided through the administration of this *Policy* will only cover standard of clinical care costs in alignment with those provided through the current CAR T-cell Therapy Program.
- Clinical trials evaluating an investigational CAR T-cell therapy product may be eligible for funding through the administration of this *Policy*.
- Clinical trials evaluating a non-CAR T-cell therapy product through the investigational arm of the clinical trial may be eligible to receive funding through other Ontario funding programs (e.g., [Systemic Treatment – Quality Based Program](#), [New Drug Funding Program](#)) and applicants should refer to the applicable program policy for further information.
- Standard of care therapies being delivered as part of a clinical trial may be eligible for funding through other Ontario funding models (e.g., [Ontario CAR T-cell Therapy Program](#),

[Provincial Drug Reimbursement Programs](#), etc.) and applicants should refer to the applicable program policy for further information.

- Although the clinical trial may treat patients without a valid Ontario Health Insurance Number, the hospital/cancer centre is only eligible to receive funding for care costs of patients with a valid Ontario Health Insurance Number.
- Although the Clinical Trial may be operated at multiple centres, only clinical trials that are operated at FACT accredited CAR T-cell therapy sites in Ontario will be funded through the administration of this *Policy*.
- Receiving CAR T-cell therapy as part of a clinical trial may impact a patient's downstream eligibility for publicly funded CAR T-cell therapy products. Eligibility for a subsequent commercial CAR T-cell therapy will be based on current Ontario CAR T-cell Therapy Program enrolment criteria. In making treatment decisions, please consider the implications, and discuss with the patient.
- Receiving CAR T-cell therapy as part of a clinical trial may impact a patient's downstream eligibility for public funding of other therapies. Please refer to the applicable program policies and procedures to determine potential restrictions. In making treatment decisions, please consider the implications and discuss with the patient.

Application and Assessment Process

Overview

The CAR T-cell therapy clinical trials application and assessment process describes how Ontario Health (Cancer Care Ontario) will intake and assess applications against set eligibility criteria.

After receiving a CAR T-cell Therapy Clinical Trial Funding Request Application, Ontario Health (Cancer Care Ontario) will provide an assessment of the funding decision to the applicant in accordance with this *Policy*.

Ontario Health (Cancer Care Ontario) reserves the right to update the CAR T-cell Therapy Clinical Trials Funding Policy. Ontario Health (Cancer Care Ontario) will initiate a review of this policy annually. Clinical trials must meet criteria outlined by the policy at the time funding is sought.

Please note that assessment of clinical trials under this *Policy* does not include funding for the CAR T-cell product used as part of the trial or other products/drugs used subsequent to the trial as part of patient management. A patient's eligibility for public cancer drug funding is determined by the existing Ontario drug funding program processes and criteria.

Application Process

An Application must be completed by the Principal Investigator of a CAR T-cell therapy clinical trial in Ontario. An application form can be obtained by contacting the program via email at OH-CCO_SSOinfo@ontariohealth.ca. A single Applicant may apply on behalf of multiple participating trial sites in Ontario.

An Application must be completed in full for each trial and submitted via email for review at OH-CCO_SSOinfo@ontariohealth.ca.

It is recommended that a completed application be submitted for review as soon as the information is available. This can be submitted prior to or simultaneously with a submission to a Research Ethics Board for review.

Upon receipt of a completed application, Ontario Health (Cancer Care Ontario) will aim to provide a full assessment to the applicant within 30 days. Turnaround time may be extended if additional information is required or if the assessment is complex and requires further information and review.

Application Screening Criteria

- Ontario Health will screen each application for completeness. Applicants will be contacted if there is missing information. Requests will not be assessed until the application is deemed complete. The onus is on the applicant to provide complete and accurate information.
- For an application to be complete, the following must be included:
 - Applicant's contact information and submitting hospital details;
 - Clinical trial identifiers, including:
 - Trial name
 - Investigator(s)
 - Participating site(s)
 - Trial number
 - Evidence of or intention to register the trial at clinicaltrials.gov or at clinicaltrialsregister.eu
 - Trial Sponsor
 - Trial Phase
 - Clinical trial funding source(s)
 - Summary of clinical trial, including:
 - Schema
 - Product name and indication

- Expected timeframe of the trial
 - Overview of next steps, if the study has positive outcomes
- Patient eligibility criteria
- Anticipated volume of Ontario patients expected to qualify for clinical care funding (per fiscal year) and total target volumes for the clinical trial.
- Confirmation of research ethics board approval
 - If pending, Ontario Health (Cancer Care Ontario) will proceed with review of the application. A conditional approval may be provided, dependant on confirmation of final research ethics board approval. Ontario Health (Cancer Care Ontario) must receive confirmation of research ethics board approval prior to entering into a funding agreement to release funding for approved applications.
- Initial published data on safety and/or efficacy (if available)
- Copy of study protocol (including patient eligibility criteria)
- Proof of funding source (e.g., funding letter)

Review Process

The review process consists of the following:

- If it is determined that an Application is complete, the Ontario Health (Cancer Care Ontario) team will assess the Application against the eligibility criteria as listed in this *Policy*.
- As needed, Ontario Health (Cancer Care Ontario) program staff will consult with disease site specific experts when reviewing applications (i.e., if clinical input is required). Program staff will take potential conflicts of interest into consideration when selecting disease site specific experts to consult on the review of an application.
- Ontario Health (Cancer Care Ontario) will notify the Applicant via email if further information is required to adjudicate the application.
- Ontario Health (Cancer Care Ontario) program staff will complete the assessment and notify the Applicant of the funding decision via email. The Applicant is responsible for communicating the outcome of the assessment and relevant information to other Ontario investigators, their hospital's Finance department, and other funders of the clinical trial, as appropriate.
- Ontario Health will enter into a funding agreement to reimburse eligible standard clinical care costs in alignment with the Ontario Health (Cancer Care Ontario) CAR T-cell Therapy Program.

Re-evaluation, Reconsideration and Resubmission

Re-evaluation: Over time, new information may emerge that may change the assessment of an application (e.g., an update to this *Policy*). The Clinical Trial must meet funding criteria at the time funding is sought. In the event of a change, the Applicant may request for a re-evaluation of their original submission by emailing OH-CCO_SSOinfo@ontariohealth.ca.

Ontario Health (Cancer Care Ontario) will aim to provide a re-evaluation to the applicant within 30 days. Turnaround times may be extended if additional information is required or for complex requests that require further consultation with disease site experts.

There are two options available to an applicant who has received a negative assessment (i.e., “not aligned with criteria”):

Resubmission: The applicant may file another submission following an initial application with an assessment of “not aligned with criteria”, if the applicant has new evidence or pertinent information that may change the assessment. To resubmit, the applicant must highlight the new information on the initially submitted application form and email it to OH-CCO_SSOinfo@ontariohealth.ca. Ontario Health (Cancer Care Ontario) will review resubmissions filed at any point after a negative assessment.

Ontario Health (Cancer Care Ontario) will aim to provide a re-assessment to the applicant within 30 days. Turnaround times may be extended if additional information is required or for complex requests that require further consultation with disease site experts.

Reconsideration: Within 30 days of the date specified on the final assessment, the applicant may request a reconsideration of an initial application or a resubmission request with a negative assessment (i.e., not aligned with criteria), if the applicant believes the assessment criteria were wrongfully applied to the application but does not have new evidence or pertinent information that may change the assessment. The applicant must file for reconsideration by email to OH-CCO_SSOinfo@ontariohealth.ca and identify and explain which criteria were wrongfully applied. The reconsideration will be reviewed by a panel, which may include disease site specific experts, Ontario Health (Cancer Care Ontario) program staff and clinical leads, who may or may not have previously assessed the application.

No new information will be allowed in the case of a reconsideration. Applicants with new information should file a resubmission, as described above.

Appendix

Acknowledgements

This Policy was produced by the Ontario Health (Cancer Care Ontario) CAR T-cell Therapy Program in partnership with the CAR T-cell Therapy Clinical Trials Working Group. Membership of the Working Group, including member name and affiliation, is listed below:

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Contact Us

Should you have any questions about this *Policy*, please contact the Ontario Health (Cancer Care Ontario) Specialized Services Oversight team (OH-CCO_SSOinfo@ontariohealth.ca).

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