



Ontario Health
Cancer Care Ontario

Chimeric Antigen Receptor (CAR) T-cell Therapy Program

Appeals Policy

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Policy Owner: Provincial Drug Reimbursement Programs, Specialized Services Oversight

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A. PURPOSE

The purpose of this *Chimeric Antigen Receptor (CAR) T-cell Therapy Program Appeals Policy* is:

- I. To clearly define the requirements for an appeal or resubmission for a CAR T-cell request that has been denied for public funding by the CAR T-cell Therapy Program.
- II. Outline the review process for resubmission and an appeal.

B. DEFINITIONS

Terms not otherwise defined in this Appeals Policy have the meanings set out in the *CAR T-cell Therapy Program Policy*.

Appeal: The Applicant believes the funding criteria for a given enrolment have been improperly applied or interpreted, and requests a review of the initial negative funding decision, but has no new evidence (or pertinent medical documentation).

CAR T-cell Therapy Program Policy: The policy used to assess individual funding requests to Ontario Health's CAR T-cell Therapy Program. This policy set out the eligibility criteria and adjudication process for public funding of CAR T-cell therapies.

Initial request: The first request for funding CAR T-cell therapy, for a specified patient for a given indication, through the CAR T-cell Therapy Program.

Resubmission: The Applicant requests a review of the initial negative funding decision and submits additional information (e.g., published literature, new pertinent medical documentation) in response to the reason(s) for rejection.

C. ELIGIBLE APPLICANTS

- I. To be eligible to appeal a negative funding decision by the CAR T-cell Therapy Program, the Applicant must be the same individual who initially applied to the program (i.e., the treating physician who submitted the initial request).

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- II. Patients cannot file a resubmission or an appeal following a negative funding decision.

D. APPEAL/RESUBMISSION REQUIREMENTS

- I. The Applicant has 60 days from the date of the decision letter to file a resubmission or appeal. After 60 days, the patient's clinical circumstances may have changed and a new request with updated clinical information will be required.
- II. For a **resubmission**, the Applicant should file a request in writing:
 - a. State the tracking number for the initial request; and
 - b. Provide additional information (e.g., pertinent medical documentation, published literature) that is responsive to the reason(s) for rejection.
- III. For an **appeal**, the Applicant should file a request in writing:
 - a. State the tracking number for the initial request;
 - b. List all of the funding criteria on the applicable enrolment form that the request failed to satisfy;
 - c. Describe how the program incorrectly applied or interpreted the funding criteria; and
 - d. Comprehensively refute the grounds for rejection.
- IV. Applicants and/or delegates should not knowingly contact the clinical expert reviewer(s) regarding the review of an appeal or resubmission.

E. FILING PROCESS

The Applicant must file an appeal electronically using the designated secure upload tool when personal health information is contained in any of the documents.

The secure upload tool is available at mft.cancercare.on.ca. Please refer to the instructions on the website for how to upload documents:

https://www.cancercareontario.ca/sites/ccocancercare/files/assets/CAR-T_MFT_Tumbleweed_User_Instructions_Final_revised_03-Dec-2019.pdf.

F. RESUBMISSION REVIEW PROCESS

- I. Upon receipt of a resubmission, the CAR T-cell Therapy Program will screen the resubmission and may request additional information from the applicant.
- II. Resubmissions that are considered “**ineligible**” include:
 - a. The applicant does not submit new information (e.g., evidence or pertinent medical documentation) that is responsive to the reason(s) for rejection of the initial request;
 - b. The applicant does not provide any rationale to refute the grounds of the rejection; or
 - c. The resubmission was submitted after 60 days from the date of the decision letter.
- III. A resubmission will be reviewed according to section J (adjudication process) of the *CAR T-cell Therapy Program Policy*.
- IV. If external clinical expert review is required, the same clinical expert reviewers who assessed the initial request will be consulted (if feasible). The roles of the external clinical reviewer are described in section J (III. External clinical expert review) of the *CAR-T cell Therapy Program Policy*.
- V. The CAR T-cell Therapy Program will notify the Applicant of the funding decision in writing.
- VI. If the initial negative funding decision is **upheld**, the Applicant can:
 - a. Request another resubmission, if they have additional information that is responsive to the rationale for rejection, within 60 days from the date of the resubmission decision letter; or
 - b. File an appeal to the CAR T-cell Therapy Program within 60 days from the date of the resubmission decision letter.

G. APPEAL REVIEW PROCESS

- I. Upon receipt of an appeal, the CAR T-cell Therapy Program will screen the appeal and may request additional information from the Applicant.

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- II. Should the Applicant submit new evidence or pertinent medical information that is responsive to the reason(s) for rejection of the initial request, the program will assess the request as a “resubmission”.

 - III. Appeals that will be considered “**ineligible**” include:
 - a. The patient clearly does not meet one or more of the funding criteria specified for the given CAR-T product and indication;
 - b. The appeal is submitted after 60 days from the date of the funding decision;
 - c. The Applicant does not provide any rationale to refute the grounds of rejection; or
 - d. Subsequent appeals for requests that were previously appealed and the initial negative funding decision was upheld.

 - IV. The CAR T-cell Therapy Program will review the appeal, funding criteria for the given CAR-T product and indication, prior decisions, and the justification for the appeal.

 - V. If there is clinical uncertainty as to whether the patient meets the funding criteria for the given CAR-T product and indication, the CAR T-cell Therapy Program will seek advice from the external clinical expert reviewer(s):
 - a. For requests that were initially assessed with clinical expert reviewers, different clinical expert reviewers will be consulted on appeal (if feasible).
 - b. For clarity, the CAR T-cell Therapy Program is not bound by the advice given by clinical expert reviewer(s) and the program will make a funding decision based on the totality of information.

 - VI. The assessment by the CAR T-cell Therapy Program will include:
 - a. a review of the request and previous decision(s) against the applicable funding criteria for the given CAR-T product and indication;
 - b. a determination of whether the grounds for Appeal are substantiated, given the applicable funding criteria; and
 - c. a review of the clinical expert reviewer(s)’ opinions (when sought).

 - VII. The CAR T-cell Therapy Program will make the decision to uphold or overturn the initial negative funding decision.

VIII. The CAR T-cell Therapy Program will inform the Applicant, in writing, of the funding decision. If the negative funding decision is upheld, the CAR T-cell Therapy Program will include the rationale for the denial.

IX. Once a decision on an appeal has been issued, subsequent appeals are not permitted.

H. TIMELINES FOR REVIEW

The CAR T-cell Therapy Program will aim to process a resubmission or appeal as quickly as possible. Due to the complexity of these cases and the need for external review, a resubmission or appeal may take up to **15 business days**. An incomplete resubmission or appeal request may result in longer turnaround times.