



Cancer Care Ontario / Ontario Public Drug Programs

Frequently Asked Questions: Public funding of cancer drugs and their administration within the context of clinical trials

Version: 3.0
Effective Date: December 12, 2016
Replaces Policy: Version 2.0 dated January 29, 2016
Policy Owner: Provincial Drug Reimbursement Programs

BACKGROUND

Cancer Care Ontario, together with the Ministry of Health and Long-Term Care (MOHLTC), recognize that clinical trials help to advance scientific understanding of cancer and its treatment and that patients may be given the option to enter into clinical trials at some point in their cancer treatment journey.

The purpose of the policy is to clarify the intent, the assessment criteria, and the review process related to the reimbursement of publicly funded cancer drugs and their administration costs when patients participate in clinical trials as part of their therapy.

This document accompanies the policy “*Public funding of cancer drugs and their administration within the context of clinical trials*” and addresses frequently asked questions.

GENERAL

1. Does the MOHLTC and/or Cancer Care Ontario fund clinical trials in Ontario?

No, neither MOHLTC nor Cancer Care Ontario directly fund clinical trials or investigational drugs.

MOHLTC provides funding for cancer drugs when they are used in accordance with specific criteria. Ontario Public Drug Programs (OPDP) administers some of this funding directly through the [Ontario Drug Benefit \(ODB\) Program](#), and some funding programs are delivered by Cancer Care Ontario on the MOHLTC’s behalf.

Cancer Care Ontario also funds administration costs (i.e., preparation and delivery of systemic treatment) when the drugs or regimens are listed as evidence-informed for funding through the [Systemic Treatment-Quality Based Program](#) (ST-QBP).

The cancer drug costs of those drugs not funded through OPDP, which are evidence-informed (i.e., older and inexpensive drugs that are not expected to be reviewed for public funding in Ontario) will be funded through ST-QBP.

2. Do the Ontario Public Drug Programs (OPDP) and Cancer Care Ontario support clinical trials research in Ontario?

While OPDP and Cancer Care Ontario do not directly fund clinical research in Ontario, both organizations are supportive of clinical research.

Note: participation in a clinical trial may lead to a patient not being eligible for public funding of a cancer drug subsequent to participation in a clinical trial.

The intent of this policy is to clarify how access to public cancer drug funding may be affected by participation in a clinical trial, both during or subsequent to a trial.

3. Does the policy only apply to publicly funded drugs through the New Drug Funding Program (NDFP)?

No, this policy applies to all publicly funded cancer drugs, including drugs funded under the:

- [New Drug Funding Program](#) (NDFP)
- [Ontario Drug Benefit \(ODB\) Program](#)
 - [Exceptional Access Program](#) (EAP), and
 - Formulary listing either as:
 - General Benefit (GB)
 - GB with Therapeutic notes
 - [Limited Use](#) (LU), or
- [Systemic Treatment-Quality Based Program](#) (ST-QBP).

PRINCIPLES

4. As a physician, how do I explain the implications of cancer drug funding eligibility as a result of participating in a clinical trial to my patient?

Cancer Care Ontario is committed to enhancing the informed consent process for patients. As such, the clinical trial application assessment form and the [assessment table](#) provide clinicians with information on when a trial design will and will not affect patients' access to publicly funded cancer drugs.

The clinical trial assessments are sent to the applicant who submitted the Clinical Trial Request Intake form to Cancer Care Ontario. The assessment table is available on [Cancer Care Ontario's Systemic Treatment Clinical Trials webpage](#).

A suggested approach would be to discuss the various treatment options after the trial with your patient - including whether or not they would be eligible for public funding.

Cancer Care Ontario has also developed a [provider fact sheet](#) which has been designed to help guide conversations between the clinician and their patient. It is intended to help clarify how access to public cancer drug funding may be affected by participation in a clinical trial. The provider fact sheet is available on [Cancer Care Ontario's Systemic Treatment Clinical Trials webpage](#).

APPLICATION PROCESS

5. Who should be the applicant? Does every participating site need to complete the Clinical Trial Request Intake form?

Cancer Care Ontario will accept an application from a **single** applicant who is applying **on behalf of** all investigators in the province. The designated applicant must be a practicing physician affiliated with an Ontario hospital who is involved in the clinical trial that is recruiting patients at his/her hospital.

6. When should I apply?

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.

7. Where do I find the application form?

The application can be found on [Cancer Care Ontario's Systemic Treatment Clinical Trials webpage](#). It is called the Systemic Treatment Clinical Trials Request Form.

8. Where can I find information about submitted or assessed applications?

This information is available in the clinical trials assessment table; it includes all assessed and under review applications. It is published weekly on [Cancer Care Ontario's Systemic Treatment Clinical Trials webpage](#).

9. What information is required and how do I obtain assistance in completing the application?

A completed application includes the

- clinical trial schema
- dosing schedule
- cancer drug(s) and indication(s) for which cancer drug funding is being requested
- cancer drug(s) and indication(s) funded by the clinical trial sponsor
- standard of care the patient would receive if not on a clinical trial

The application must clearly identify the treatment algorithm for all study arms subsequent to trial participation. This includes an explanation of patient management if

- The patient is withdrawn from study due to excessive toxicity
- There is disease progression
- The patient refuses further participation on the trial
- There is disease recurrence after the trial is completed

Questions can be directed to clinicaltrials@cancercare.on.ca. If required, Cancer Care Ontario program staff will provide assistance in completing the application.

10. Are there any circumstances when an application is not required?

The policy is not intended to assess imaging studies, supportive care studies or studies that are observational in nature.

An application is required when an applicant is seeking

- funding for the cost of drug administration or delivery, or
- confirmation of whether patients participating in a systemic treatment clinical trial are eligible to receive publicly funded cancer drugs within or subsequent to a clinical trial.

11. Should an application be submitted when a publicly funded cancer drug is being paid by the study sponsor during the trial?

Yes, because participation in a clinical trial may lead to a patient not being eligible for public funding of a cancer drug subsequent to a clinical trial.

The assessment will be communicated by Cancer Care Ontario to the applicant via the assessment form.

12. Why is Cancer Care Ontario assessing the funding of all publicly funded cancer drugs, even those covered under the MOHLTC's Ontario Drug Benefit Program?

Cancer Care Ontario is implementing a clinical trials policy to ensure there is funding consistency for publicly funded cancer drugs used within the context of clinical trials.

MOHLTC program staff is consulted on applications that involve drugs funded under the [Exceptional Access Program](#) (EAP) and drugs with [Limited Use](#) (LU) criteria.

13. My clinical trial is underway or is almost completed. However, I have never submitted a Clinical Trial Request Intake form. Should I still submit an application?

Yes, please complete an application - even if the trial is near completion.

Cancer Care Ontario may identify additional potential policy implications in the context of its evaluation which will be communicated to the applicant via the assessment form. Cancer Care Ontario will clarify whether cancer drugs used after trial are aligned with pertinent public drug funding policies.

This information will also enhance the informed consent process by providing guidance to investigators when a trial design may affect a patient's ability to access publicly funded cancer drugs subsequent to trial participation.

14. Is an assessment required for every clinical trial in Ontario?

The intent of the clinical trials policy is to clarify how access to public cancer drug funding may be affected by participation in a clinical trial, both during or subsequent to a trial.

Cancer Care Ontario is committed to supporting the informed consent process, therefore, an application for **every applicable systemic treatment clinical trial** should be submitted.

An application is required when an applicant is seeking

- funding for the cost of drug administration or delivery, or
- confirmation of whether patients participating in a systemic treatment clinical trial will affect access to publicly funded cancer drugs within or subsequent to a clinical trial.

The policy is not intended to assess imaging studies, supportive care studies or studies that are observational in nature.

APPLICATION SCREENING CRITERIA

15. Why do I have to submit the treatment algorithm for all study arms subsequent to trial participation?

Cancer Care Ontario will clarify whether cancer drugs used subsequent to trial are aligned to public drug funding policy.

This information will also enhance the informed consent process by providing guidance to investigators when a trial design will affect a patient's ability to access publicly funded cancer drugs.

All treatment options after the clinical trial should be identified in the application

ASSESSMENT CRITERIA

16. Has a clinical trial always been considered a line of therapy?

As a general principle, a cancer drug used within a clinical trial is considered a line of therapy.

In certain circumstances, it may be reasonable to consider the cancer drug, biologic or regimen used within a clinical trial as an investigational line (i.e., not a line of therapy).

A drug, biologic, or regimen is generally considered an investigational line if any of the following applies:

- Sufficient evidence does not exist for that cancer drug in that type of cancer and treatment setting (e.g., metastatic or adjuvant).
- The cancer drug does not have a Health Canada Notice of Compliance (NOC) for the requested indication.
- The cancer drug is used in a dose, route or schedule substantially different from the publicly funded method of administration.
- The cancer drug is used in combination with other drugs for an indication for which the combination is not publicly funded even if each of the individual agents is publicly funded for the clinical indication.

17. My clinical trial uses an investigational agent that does not have a Health Canada Notice of Compliance. Patients will be permitted to cross over to a publicly funded standard of care in circumstances of progression or toxicity. If the agent that would be used at cross over is only publicly funded as a "first line" agent, would the patient be eligible for funding in this circumstance?

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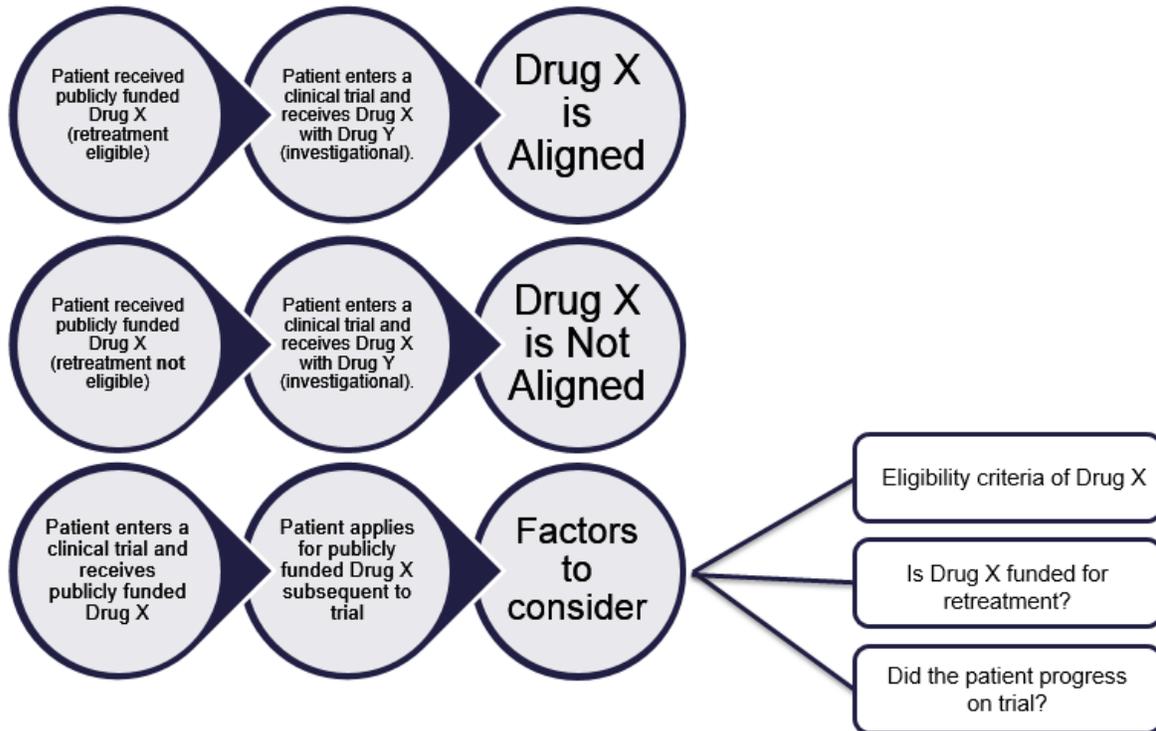
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- The cancer drug is used in combination with other drugs for an indication for which the combination is not publicly funded even if each of the individual agents is publicly funded for the clinical indication.

18. How does Cancer Care Ontario assess an application which involves a drug that is used in the retreatment setting?

Cancer Care Ontario will consider the following factors in the assessment of the application.



19. Can I request an exception for funding of a publicly funded cancer drug that does not meet the current eligibility criteria?

No, the use of the publicly funded cancer drug within a clinical trial must be for an indication that is currently publicly funded in Ontario and must meet current cancer drug funding policy.

REVIEW PROCESS

20. Who reviews and assesses the applications?

Cancer Care Ontario program staff assess the applications against the assessment criteria. They may consult with clinical advisors, MOHLTC program staff (i.e., when requests involve cancer drugs funded through the [Exceptional Access Program](#) (EAP) or on the ODB formulary as General Benefit with Therapeutic notes or [Limited Use](#) (LU), or where interpretation of the clinical trials policy is required), and disease site specific experts (i.e., if clinical input is required).

21. How long will the review process take?

Upon receipt of a completed application, Cancer Care Ontario will aim to provide a full assessment to the applicant within 30 days.

Cancer Care Ontario's turnaround time may be extended if additional information is required or if the assessment is complex and requires further consultation with disease site experts and the MOHLTC.

Cancer Care Ontario estimates that approximately 30% of applications will require further consultation, resulting in an estimated 60-day turnaround time.

Turnaround times are publicly reported on the clinical trials assessment table which can be found on [Cancer Care Ontario's Systemic Treatment Clinical Trials webpage](#).

22. Does Cancer Care Ontario have an informal expedited review process?

No, it is recommended that applicants submit a completed application 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, Cancer Care Ontario will aim to provide a full assessment to the applicant within 30 days.

Cancer Care Ontario's turnaround time may be extended if additional information is required or if the assessment is complex and requires further consultation with disease site experts and the MOHLTC.

Cancer Care Ontario estimates that approximately 30% of applications will require such further consultation, resulting in an estimated 60-day turnaround time.

Turnaround times are publicly reported on the clinical trials assessment table which can be found on [Cancer Care Ontario's Systemic Treatment Clinical Trials webpage](#).

POST-ASSESSMENT QUESTIONS

23. Does a positive assessment (i.e., aligned) guarantee funding?

No, an application for assessment of a clinical trial will not necessarily ensure there will be funding for the cancer drugs used during or subsequent to the trial.

A patient-specific NDFP enrolment, EAP application or LU prescription by a referring clinician is still required to confirm patient eligibility.

A patient's eligibility for public cancer drug funding is determined by the existing NDFP, EAP, LU or other drug funding program processes and criteria.

Clinicians must apply directly to the EAP if requesting EAP-funded drugs within or subsequent to clinical trial participation. Clinicians must document the trial identifier and the use of the investigational agent(s) in the EAP application. Patients must be eligible to receive benefits through the [Ontario Drug Benefit \(ODB\) Program](#).

Over time, new information may emerge that may change an application assessment (e.g., a new publicly funded cancer drug or a revision to an existing drug funding policy). In such an event, Cancer Care Ontario will re-evaluate the application(s), inform the original applicant if there is a change in the assessment, and update the clinical trials assessment table posted on [Cancer Care Ontario's Systemic Treatment Clinical Trials webpage](#).

POLICY EVALUATION

24. How will Cancer Care Ontario formally evaluate this policy?

Cancer Care Ontario and the Ontario Public Drug Programs are committed to transparency and will continue to publish clinical trial assessment outcomes and policy evaluation metrics on a regular basis on the [Cancer Care Ontario's Systemic Treatment Clinical Trials webpage](#).