

### CASE-BY-CASE REVIEW PROGRAM

#### HEALTH-CARE PROVIDERS FREQUENTLY ASKED QUESTIONS

#### 1. What is the Case-by-Case Review Program?

The Case-by-Case Review Program (CBCRP) considers funding requests for cancer drugs for cancer patients who have a rare clinical circumstance that is immediately life threatening (defined as: death is likely within a matter of months) and who require treatment with an unfunded drug, because there is no other satisfactory and funded treatment option.

#### 2. Who is eligible for CBCRP funding?

Cancer patients who have rare life-threatening circumstances (i.e., death is likely to occur within a matter of months) and for whom there is no satisfactory alternative treatment.

In order to receive CBCRP drug coverage, patients must be residents of Ontario and have a valid Ontario Health Card. For drugs that will be obtained from retail pharmacies, patients need to be eligible for benefits under the [Ontario Drug Benefit Program](#) and/or the [Trillium Drug Program](#).

#### 3. Which drugs are eligible for CBCRP funding?

CBCRP makes patient-specific rather than drug-specific funding decisions. Oncologists can apply for any cancer drug that is currently unfunded in Ontario, provided their patient's case meets the CBCRP eligibility criteria (*see Question 4*). CBCRP will accept requests for funding of cancer drugs administered in hospital (e.g., intravenous drugs) or for out-patient, community use (e.g., *oral drugs*).

These drugs are not eligible:

- Non-cancer drugs
- Drugs used in the supportive treatment of cancer (e.g., filgrastim, aprepitant)
- Drugs reviewed and/or under review by the Committee to Evaluate Drugs (CED) for the requested indication

#### 4. What are the CBCRP eligibility criteria?

Patients who meet all the eligibility criteria of the [Case-by-Case Review Policy for Cancer Drugs](#) will be considered for funding.

The Eligibility criteria:

- Drug is intended to treat an existing cancer
- The patient has a **rare** clinical circumstance that is immediately life threatening (i.e., death is likely to occur within months)
- There is no other comparable clinical alternative
- There are no other funding options (e.g., [Ontario Drug Benefit](#), [New Drug Funding Program](#), [Exceptional Access Program](#)) exist
- The patient cannot enroll in a clinical trial
- Evidence primarily shows that the drug will prolong survival  
**\*\*NB:** For cases where survival evidence is weak and survival is an unlikely treatment goal for the stage of the disease, the case still may be considered if there is evidence that the treatment has a clinically significant impact on quality-of-life (QOL).
- The treatment may avoid or defer other health-care costs

The CBCRP is not intended to provide provisional funding of a regimen in advance of a formal evaluation through the regular review mechanism.

## 5. How do I apply to CBCRP?

Requests for funding will be accepted only from the treating oncologist, who must complete the *CBCRP Request Form* and submit it, along with relevant supporting documentation, to CCO via a secure online upload tool.

Electronic forms for submitting requests are available at the [CCO website](#).

## 6. What is CCO's review process?

CCO reviews each request, in consultation with expert reviewers if necessary, and makes a funding recommendation to the Executive Officer (EO) of Ontario Public Drug Programs (OPDP).

For each request, CCO will:

- Verify that the Request form is complete
- Conduct an internal review, including any necessary literature reviews, to confirm eligibility as per the *Case-by-Case Review Policy for Cancer Drugs*.
- Obtain independent opinions from at least two expert reviewers (oncologists or hematologists as appropriate). At least one reviewer will be a disease-site specialist. (*\*In cases in which internal reviewers determine that the case clearly does not meet the eligibility criteria, there will not be an external review process*).
- Summarize the case's congruence with the policy and provide a funding recommendation to the Executive Officer (EO).

## 7. Who makes the final funding decision?

The EO makes the final funding decision.

## 8. How long does it take to get a funding request decision?

CBCRP is not intended for acute or emergency therapy. The decision-making process includes verification of eligibility, literature reviews, expert review and a final funding decision made by the EO. To help expedite the review process, the

physician is requested to provide literature on the efficacy and safety of the drug at the time he/she makes application. CBCRP Request forms are screened upon receipt for completeness. CCO will inform applicants if additional information is required. CBCRP will aim to provide a funding decision within two weeks of receiving a completed request accompanied by all relevant supporting documents. However, timelines may vary depending on the complexity of the case.

#### 9. How many treatment cycles will be approved at one time?

The time frame of approval will be determined on a case-by-case basis. Factors such as the best-available evidence, treatment plan, and expert opinion will be considered in the decision. Requests for renewals will be accepted, but the physician must provide evidence of a treatment response.

#### 10. What is the expected turnaround time for a renewal?

Requests for renewals also are subject to a review process that includes an assessment of the treatment response by expert reviewers. CBCRP will aim to provide a funding decision within two weeks of receiving a properly completed *CBCRP Renewal Form* with all necessary supporting documentation. Oncologists are encouraged to apply at least three (3) weeks prior to the end of the funding period.

#### 11. How are hospital-administered drugs reimbursed?

CBCRP will fund hospital-administered cancer drugs (*e.g., intravenous drugs*) which have been evaluated and approved for coverage. CBCRP does not reimburse individuals for the cost of cancer drugs; instead, reimbursements are made to Ontario's Regional Cancer Centres (RCCs), Princess Margaret Hospital (PMH), and more than 70 community hospitals affiliated with CCO. To be reimbursed, hospitals must submit treatment data for each patient. Visit [CCO website](#) for further instructions on how to invoice CCO.

#### 12. How are drugs for outpatient community use (e.g., oral drugs) reimbursed?

Cancer drugs for outpatient, community use (*e.g., oral drugs*) are funded under the [Ontario Drug Benefit Program](#) (ODB) and the [Trillium Drug Program](#). Physicians should give their patients a copy of the CBCRP approval letter to take to the pharmacy when they have their prescription filled. Pharmacies should process this claim through the Health Network System (HNS) as per the applicable sections of the Ontario Drug Benefit Formulary and the *Ontario Drug Benefit Act*.

Oncologists should verify that their patients have drug coverage under [ODB](#) or the [Trillium Drug Program](#) before they apply to CBCRP.

#### 13. What are my options if funding is denied?

Within 30 days of the decision, there are two options:

- i. If the oncologist has additional information that addresses the reasons for rejection then he/she can file a **Resubmission**.
- ii. If the oncologist has no new information that addresses the reason for rejection, but believes the policy has been improperly applied, then he/she can file an **Appeal**. (Refer to the [CBCRP Appeals Policy](#) for details).

#### **14. Are drugs that have not been approved by Health Canada eligible for funding?**

CBCRP will accept request for drugs that do not have a Notice of Compliance (NOC) and Drug Identification Number (DIN), providing that approval has been obtained from Health Canada's [Special Access Programme](#) (SAP).

#### **15. If my drug is not approved for funding by ODB or NDFP, can I apply to CBCRP?**

This program is not intended for drugs and indications where a clear decision on funding has been made. In Ontario, the Executive Officer (EO) of the Ontario Public Drug Programs, based on recommendations by the Committee to Evaluate Drugs (CED), makes the final decision whether to fund a drug under the New Drug Funding Program (NDFP) and other public drug programs. If the requested drug and indication has been reviewed and rejected under this process, it will not be eligible for CBCRP funding.

#### **16. Are new drug therapies not yet approved by MOHLTC eligible for CBCRP funding?**

The CBCRP is not intended to provide provisional funding of a regimen in advance of a formal evaluation through the regular review mechanism. For more information on how drugs are approved, go to the [MOHLTC website](#).

#### **More Information**

For more information about the Case-by-Case Review Program, email [cbcrp@cancercare.on.ca](mailto:cbcrp@cancercare.on.ca)