

Cancer Care Ontario

Action Cancer Ontario

CASE-BY-CASE REVIEW PROGRAM (CBCRP)

CASE-BY-CASE REVIEW POLICY FOR CANCER DRUGS

Version: 3.0

Effective Date: October 2013

Replaces Policy: Case-by-Case Review Policy for Cancer Drugs, November 8, 2011

Policy Owner: Provincial Drug Reimbursement Programs

Contents

A. PURPOSE..... 1

B. SCOPE..... 1

C. ELIGIBLE APPLICANTS..... 1

D. ELIGIBLE PATIENTS..... 1

E. APPLICATION CRITERIA 2

F. FUNDING CRITERIA..... 3

G. REVIEW PROCESS..... 5

H. FINAL FUNDING DECISION 6

I. CONDITIONS OF REIMBURSEMENT 7

J. RENEWALS 7

K. OPTIONS IN THE EVENT OF A NEGATIVE FUNDING DECISION..... 8

L. TIMELINES FOR REVIEW 9

M. POST- TREATMENT DOCUMENTATION REQUIREMENTS 9

A. PURPOSE

The purpose of the *Case-by-Case Review Program (CBCRP) Policy for Cancer Drugs* is to:

- I. define the requirements for an eligible request to the CBCRP, a program operated by Cancer Care Ontario (CCO), and
- II. to outline the adjudication and reimbursement process.

B. SCOPE

- I. The CBCRP considers funding requests (**CBCRP request**) for oral and injectable cancer drugs for cancer patients who have rare clinical circumstances that are immediately life threatening, and who require treatment with an unfunded drug because there is no other satisfactory and/or funded treatment.
- II. The CBCRP is not intended to provide interim drug funding for indications (i.e., reason for use) that are currently being reviewed or expected to be reviewed for public funding in Ontario. Manufacturers are aware of the timeframe for funding decisions and it is at their discretion to provide a compassionate supply.
- III. In cases where CBCRP drug coverage is required to fund continued treatment for a drug that was previously funded by a clinical trial, or paid for by other means (such as a third party payor), the request must satisfy all policy criteria (*section E. and F.*) at the time therapy was initiated.
- IV. The CBCRP is intended for patients who require prompt drug funding for cancer therapy in the ambulatory setting. The CBCRP is not intended to fund drugs for acute or emergency use.

C. ELIGIBLE APPLICANTS

Patients cannot make a CBCRP application. The CBCRP applicant (**Applicant**) must be:

- I. a physician who specializes in the treatment of cancer (e.g., medical oncologist, hematologist); and
- II. a physician who is licensed to practice in Ontario (i.e., holds a valid license from the College of Physicians and Surgeons of Ontario).

D. ELIGIBLE PATIENTS

To receive drug coverage under the CBCRP, patients must be residents of Ontario and have a valid Ontario Health Card. If the CBCRP coverage is being requested for a drug that is not administered in a hospital or cancer centre, but rather will be dispensed by a retail pharmacy, the patient must also be eligible for benefits under the Ontario Drug Benefit Program and/or the Trillium Drug Program.

E. APPLICATION CRITERIA

Application criteria will be used to determine whether the request is eligible for consideration under the CBCRP Policy. Requests that do not fulfill all of the **application criteria** will not be considered for CBCRP funding.

1. DRUG ELIGIBILITY

- I. The drug must be intended to treat an existing cancer. Funding requests for drugs used in the supportive treatment of cancer (e.g., anti-emetics, colony-stimulating factors) are not eligible for funding.
- II. The drug must be intended for out-patient use or administration (i.e., not for hospital in-patient use) in Ontario.
- III. The drug must be available on the Canadian market (i.e., has a Drug Identification Number) or the Applicant must provide evidence through the *CBCRP Request Form* that approval to import the drug has been obtained through Health Canada's [Special Access Programme](#) (SAP).

2. OTHER FUNDING OPTIONS:

The patient must have no other funding option available to him/her for the requested drug. For the requested indication, each of the following must be true for the request to be eligible:

- I. the patient cannot access the drug through a clinical trial;
- II. the patient cannot receive a compassionate supply or funding from the requested drug manufacturer;
- III. for hospital-administered drugs, the requested drug is normally expected to be funded by the treating hospital; and
- IV. the patient is not already receiving funding through another public drug funding program for the requested drug (e.g., Exceptional Access Program, New Drug Funding Program, etc.).

3. PUBLIC FUNDING STATUS:

The drug for the requested indication cannot be currently funded or expected to be considered for funding under drug programs offered by Ontario Public Drug Programs (OPDP).¹ As such, requests that are ineligible for CBCRP funding consideration include the following:

- I. The drug for the requested indication is expected to be reviewed for public funding in Ontario (e.g., pending review by the pan-Canadian Oncology Drug Review or Common Drug Review, indications approved by Health Canada or the U.S., Food and Drug Administration, etc.).
- II. The drug for the requested indication is under review for public funding in Ontario.
- III. The drug for the requested indication has been reviewed and funding criteria has been established under another public drug funding program (e.g., Exceptional Access Program, New Drug Funding Program, etc.).
- IV. The drug for the requested indication has been reviewed and rejected for public funding in Ontario.

Note: For the purpose of assessing **E.3**, an “indication” refers to the patient’s type of cancer, regardless of the line of therapy.

F. FUNDING CRITERIA

The request will be evaluated against the following **funding criteria** to determine whether it aligns with the intent of the program.

1. URGENCY

The patient presents with an immediately life-threatening condition (i.e., the patient’s condition is such that a loss of life is likely to occur within a matter of months).

2. RARITY

The patient must have a rare clinical circumstance (e.g., the cancer itself may not be rare, but the patient’s comorbidities, allergies, severity of symptoms, or other factors make the clinical situation rare) such that less than 25 similar requests are anticipated per year.

¹ In situations where a cancer drug has been reviewed by the Committee to Evaluate Drugs (CED) and the Ministry is in prolonged negotiations with the manufacturer but the Executive Officer (EO) has not made a final funding decision, requests will be considered on a case-by-case basis for those individuals who have been urgently hospitalized due to an immediate life-, limb-, or organ threatening complication. The request must be for a cancer drug therapy that is directly related to the clinical condition that has resulted in the hospitalization and the drug in question must be under review by the ministry. Interim drug funding will be limited to a maximum six month approval and will begin once the patient is discharged from hospital. Further coverage may not be approved once final criteria for funding have been established.

3. EVIDENCE

- I. The Applicant must submit published evidence supporting the use of the drug for the requested indication. The patient's apparent response to treatment, in itself, is insufficient evidence of effectiveness.
- II. Based on the best available evidence and the totality of evidence, the therapy is expected to provide a clinically meaningful outcome in this patient. The following factors will be evaluated:
 - a. **Level of evidence:** The minimum level of evidence required is a case- series or multiple-case reports where $n \geq 25$ in total. Ideally randomized controlled trial (RCT) data should be available; individual case reports and expert opinion provide the lowest level of evidence and may be considered insufficient data to support a CBCRP request.
 - b. For requests where direct evidence is below the minimum level required due to the rarity of the cancer or clinical presentation, the CBCRP may accept and consider data from comparable, and potentially more common, clinical circumstances as supporting evidence. The clinical justification for this extrapolation must be provided.
 - c. **Clinical Benefits:** Under this clinical circumstance, evidence supports survival of a significant duration (e.g., prolong survival by months) with the requested drug. For requests where survival evidence is weak and survival is an unlikely treatment goal given the nature and stage of the disease, quality of life may be considered.
 - d. **Safety:** Under this clinical circumstance, evidence supports that treatment-related toxicity is acceptable and manageable.
 - e. **Overall Impact:** The expected clinical outcomes from the therapy must be meaningful and superior when compared to all other available treatment options. The applicant must justify that the potential benefits of therapy outweigh the risks.

4. ALTERNATE TREATMENT OPTIONS

The patient has exhausted all other treatment options or there is a lack of effective treatment options for the patient's clinical circumstance. Specifically, each of the following options has been deemed a therapeutic failure or is clinically inappropriate:

- I. non-pharmacological alternatives;
- II. comparable alternatives available through the New Drug Funding Program or the Ontario Drug Benefit Formulary;
- III. comparable alternatives available through the Ministry's Exceptional Access Program; and
- IV. any other comparable cancer regimens, including those that can be offered as part of a local clinical trial.

5. COST OF REQUESTED DRUG

- I. Treatment with the requested drug is reasonably expected to avoid or defer other health care costs (e.g., hospitalization, physician visits, etc.).
- II. In cases where the cost impact of the requested drug is significant, a more detailed analysis of cost and benefit as it relates to the requested drug may be conducted before a funding decision is made.

G. REVIEW PROCESS

The review process for **new requests** is comprised of the following components:

- I. **Application Completeness:** CCO will screen each request for completeness. In the case of missing information, CCO will contact the Applicant as necessary. Applications which remain incomplete after 10 days from the date of submission will be closed. The application will be deemed incomplete if any of the following are missing:
 - Mandatory questions on the Request Form
 - Clinical documents
 - Supporting evidence
- II. **Evaluation of Application Criteria:** Upon receipt of a complete application, CCO will assess the request against the application criteria (*section E.*). If necessary, CCO may consult with external clinical experts to verify application criteria. Requests that **do not meet any one of the application criteria** are "CBCRP Ineligible" and will not be further assessed.

- III. **Evaluation of Funding Criteria:** CCO will assess the request against the funding criteria (*section F.*). In the evaluation, CCO will consider the clinical information and justification for therapy submitted by the applicant, the best available evidence and expert opinion. This evaluation will be omitted for requests that are ‘CBCRP Ineligible.’”

- IV. **External Clinical Expert Opinion:**
CCO will forward requests for independent external review by clinical experts:
 - Clinical experts may be either oncologists or hematologists as appropriate. At least one clinical expert must be a specialist with an understanding of the disease condition for which the request is being submitted.

 - Clinical experts will provide an opinion on clinical appropriateness to CCO by considering the patient’s clinical situation, best available evidence, and intent of this policy.

 - Requests that definitively do not meet any of the application criteria or the funding criteria will not be forwarded for external review.

- V. **Funding Recommendation:** CCO will summarize how the request aligns with the policy and provide a funding recommendation to the Executive Officer. For a **positive funding** recommendation, each of the following must be met:
 - a. The request satisfies all of the Application Criteria.
 - b. Upon evaluation against the Funding Criteria, the request meets the intent of the policy.
 - c. At least two clinical experts support the use of the drug for the requested indication in this patient. In cases of divergent clinical opinions, a third opinion by a clinical expert will be obtained.

H. FINAL FUNDING DECISION

- I. The Executive Officer will review each CBCRP request and will make the final funding decision with respect to the drug. Requests that are deemed “CBCRP Ineligible” (see G.II) will be reviewed by the Executive Officer, as necessary.

- II. CCO will inform the Applicant, in writing, of the Executive Officer’s final decision.

- III. When a decision is made not to approve a CBCRP request, CCO will inform the Applicant, in writing, of the rationale for rejection.

I. CONDITIONS OF REIMBURSEMENT

For approved requests, the cost of the drug will be reimbursed and is subject to the conditions outlined below:

- I. The dose, frequency, duration, and route of administration that will be approved for the drug will be determined on a case-by-case basis, and based on the information provided in the application. The decision will be based on the Applicant's proposed treatment plan, the best available evidence, and clinical expert opinion provided to CBCRP during its evaluation of the request. In the event of treatment plan changes, the Applicant should contact the CBCRP to confirm continued eligibility and reimbursement.
- II. Hospital-administered cancer drugs (*e.g., intravenous drugs*), will be funded by the CBCRP as follows:
 - The CBCRP will directly reimburse CCO and affiliated hospitals, for doses administered, where the patient is receiving treatment. Doses administered in a private clinic will not be reimbursed.
 - The reimbursement rate will be based on the current Provincial Drug Reimbursement Programs price list. If the approved drug is not on this list, the reimbursement rate will be based on the hospital acquisition cost.
 - In order to be reimbursed, the hospital must submit treatment data for each patient on a monthly basis and invoices, as requested, by the CBCRP.
- III. Cancer drugs for outpatient, community use (*e.g., oral drugs*) will be funded under the Ontario Drug Benefit Program (ODB) and the Trillium Drug Program.
- IV. Date of coverage begins on the "effective date" and extends to the "expiry date" stated on the approval letter issued by the CBCRP to the applicant. Doses administered **prior to the effective date will not be reimbursed.**
- V. If there is a significant change in patient circumstances, treatment plan, or a lengthy delay (*e.g., > 30 days*) to initiating treatment, the CBCRP may request additional documentation and/or reassess eligibility prior to providing reimbursement. Failure to provide the required documentation will result in the termination of coverage.

J. RENEWALS

- I. Once the duration of drug coverage is near expiration, the CBCRP will accept requests for renewals (**Renewal**).
- II. To allow for adequate review time, a request for Renewal should be initiated at least 3 weeks prior to the patient finishing his/her current supply of the requested drug. Doses dispensed or administered in the absence of approved funding may not be reimbursed.

- III. A renewal will be evaluated on the following criteria:
 - a. **Treatment response:** There must be evidence of an objective measure(s) of response;
 - b. **Toxicity:** Treatment-related toxicity is acceptable and manageable
 - c. **Expected Outcome:** At the time of renewal, there have been no significant changes in the patient's clinical condition, treatment plan, or other factors to suggest that the outcome of therapy for which the drug was initially approved is no longer expected.
- IV. CCO reviews each Renewal, in consultation with clinical experts, and makes a funding recommendation to the Executive Officer (EO). For a positive funding recommendation, the criteria stated in J.III must be satisfied and the opinion of at least one clinical expert supports continued therapy.
- V. The final funding decision on a Renewal is as per Section G.

K. OPTIONS IN THE EVENT OF A NEGATIVE FUNDING DECISION

Where a negative funding decision has been rendered by the Executive Officer, the Applicant has the following options:

- I. Within thirty days of the funding decision being communicated to the Applicant by the CBCRP, the Applicant may:
 - a. Resubmit additional evidence in response to the reason for the rejection **(Resubmission)**. A Resubmission will be assessed as per **sections E. through G.** of this Policy. The clinical experts who assessed the initial CBCRP request may also assess the Resubmission;
 - or**
 - b. Appeal the funding decision; where there is no new additional evidence, but the Applicant feels that the CBCRP policy has been improperly applied to his/her request **(Appeal)**. Appeals will be assessed in accordance with the *CBCRP Appeals Policy*.
- II. After thirty days of a negative funding decision being communicated to the Applicant by the CBCRP, the Applicant must submit a new application in order for the request to be re-considered by the CBCRP.

L. TIMELINES FOR REVIEW

Upon receipt of a complete application, the CBCRP will aim to provide a funding decision from the Executive Officer within two weeks.

M. POST- TREATMENT DOCUMENTATION REQUIREMENTS

Upon completion of therapy or if treatment is discontinued for any reason, the CBCRP may, in its sole discretion, request that the Applicants provide certain follow-up information regarding patient response and program measures. This information will be used by CCO planning and program management purposes.