



Case-by-Case Review Program (CBCRP) Request Form

Requests for funding under the CBCRP are adjudicated against the eligibility criteria set forth in the Case-by-Case Review Policy for Cancer Drugs.

Requests for cancer drugs for out-patient use (e.g. oral agents) are accepted but patients must have coverage under the Ontario Drug Benefit Plan in order to be reimbursed (if approved).

This Request Form is for **NEW REQUESTS** under the CBCRP and should be completed before the first dose of the requested drug is dispensed. Funding is not retroactive.

SCREENING CHECKLIST

Please review the following eligibility questions prior to completing this form

If you answer NO to any of the following questions, your request is not eligible for CBCRP funding:

1. Does your patient have a life-threatening circumstance (i.e. expected to die within a matter of months)?
2. If this drug is not approved by Health Canada, have you obtained approval from the Special Access Programme (SAP)? (Drugs not approved by Health Canada will only be reviewed by CBCRP, if prior SAP approval has been obtained)

If you answer YES to any of the following questions, your request is not eligible for CBCRP funding:

3. Is the requested drug to be used as supportive therapy? (e.g., anti-emetics, colony-stimulating factors)
4. Can a free supply of the drug be obtained from a manufacturer's compassionate access program?
5. Could the patient access this drug via a local clinical trial?
6. Is the drug for the requested indication listed on the pan-Canadian Oncology Drug Review's website as being reviewed or pending review? (Refer to "Find a Review" at <http://www.pcodr.ca>)

Section 1: Applicant Information

Treating Oncologist

First Name	<input type="text"/>	Last Name	<input type="text"/>	CPSO No.	<input type="text"/>
Telephone	<input type="text"/>	Fax	<input type="text"/>	email	<input type="text"/>
Affiliated Hospital /Cancer Centre		<input type="text"/>			

If the treating oncologist is not the primary contact person for questions relating to this request, enter the contact information for the **primary contact person**:

First Name	<input type="text"/>	Last Name	<input type="text"/>
Telephone	<input type="text"/>	Fax	<input type="text"/>
email		<input type="text"/>	

Section 2: Patient Information

First Name Last Name Postal Code
 Date of Birth (DD/MM/YY) Health Card No. Chart No. *if known*
 Gender Male Female Other Height (cm) Weight (kg) BSA (m2)

Section 3: Patient Medical History

a. Cancer Diagnosis (*i.e., requested indication*)

b. Grade of Cancer (optional) c. Cancer Stage Clinical Pathological

d. Performance Status Score e. Scale ECOG Karnofsky

f. Relevant Comorbidities
(information used by reviewers to assess benefits vs. risks)

g. Concomitant Medications
(information used by reviewers to assess benefits vs. risks)

h. In the chart below, list all drug and non-drug treatment interventions (e.g., chemotherapy, surgery, radiation, etc.) that this patient has tried for the requested indication.

Start Date	Treatment Intervention	Dose	Frequency	Duration or No. of Cycles	Response to Therapy (select all that apply)
					<input type="checkbox"/> Adequate response <input type="checkbox"/> Inadequate response <input type="checkbox"/> Unacceptable toxicity, specify below <input type="checkbox"/> Other, specify below <input type="text"/>
					<input type="checkbox"/> Adequate response <input type="checkbox"/> Inadequate response <input type="checkbox"/> Unacceptable toxicity, specify below <input type="checkbox"/> Other, specify below <input type="text"/>
					<input type="checkbox"/> Adequate response <input type="checkbox"/> Inadequate response <input type="checkbox"/> Unacceptable toxicity, specify below <input type="checkbox"/> Other, specify below <input type="text"/>

Section 4: Treatment Regimen

a. Drug(s) Requested b. Dosage Form IV IM PO Other

c. DIN (if known or applicable)

d. Where will this patient be treated? Hospital/Cancer Centre Specify:

Out-patient community (e.g., patient's home)

Other; Specify

e. Planned Treatment Regimen
List the dose, frequency, and route of administration for the requested drug. Indicate if used in combination with another regimen or treatment modality.

f. The above treatment regimen should be cited in the literature. Explain the rationale for any regimen modifications (e.g., dose, frequency):

g. Planned Duration of Therapy No. of Cycles or No. of Months

h. Anticipated start date for administration of the requested drug

i. Describe how the treatment response will be assessed and the time frame for evaluation. (e.g., CT scan after 8 weeks of therapy)
* Used by reviewers to determine initial duration of approval

j. What are the "stopping criteria" to determine if this therapy is ineffective for this patient?

k. Treatment Cost (if known): Cost per unit (e.g., mg, IU, tablet) or standard pack size (e.g., per vial or per bottle)

l. Have you applied to any of the following funding sources? NO YES (select all that apply in the below chart)

<u>Source</u>	<u>Outcome</u>	
<input type="checkbox"/> Exceptional Access Program	<input type="radio"/> Rejected	<input type="radio"/> Re-directed to CBCRP
<input type="checkbox"/> New Drug Funding Program	<input type="radio"/> Rejected	<input type="radio"/> Re-directed to CBCRP
<input type="checkbox"/> Manufacturer's Program (e.g., Patient Assistance Program)	<input type="radio"/> Rejected	<input type="radio"/> Partial Coverage
<input type="checkbox"/> Hospital Budget	<input type="radio"/> Not covered for this indication	

m. Are you currently receiving funding for any part of the treatment regimen from another public program? (e.g., ODB, EAP, NDFP?)

No Yes, specify drug(s) and program:

n. Why can't this patient access the requested drug via a clinical trial in Ontario.

- There are no clinical trials for this drug and the patient's type of cancer.
- The patient has been assessed and did not meet the clinical trial eligibility criteria.
- Other, specify:

Section 5: Clinical Rationale

a. What is the incidence of your patient's type of cancer? (cite references)

b. Provide an estimate of the number of patients per year, in Ontario, that could be treated with the planned treatment regimen.

c. Explain why your patient has a rare clinical circumstance.

d. **Without** treatment, what is your best estimate of how long this patient will live (in months)?

e. **With** the requested treatment, how much longer is the patient expected to live? (e.g., prolong survival by an additional 1-2 months)

f. Why are other treatment options (drug or non-drug) not appropriate for this patient (e.g., drug allergies, contraindications, adverse effects, unfunded treatment)

g. Why is a clinical trial with another intervention not an option for your patient?

- A clinical trial in Ontario is not available for your patient's type of cancer.
- A clinical trial with another intervention is an inferior option for this patient.
- Patient was assessed for clinical trials and is not eligible.
- Patient was not assessed for clinical trials but is likely ineligible.
- Other, specify:

h. How will treatment with the requested drug improve the quality of life of this patient? *Specify the symptoms that are expected to improve.*

i. Summarize the evidence from published data that supports the clinical effectiveness of the requested regimen. *(Describe response rates, impact on progression-free and/or survival)*

j. Does this patient have any absolute or relative contraindications to using the requested drug.

NO YES, specify:

k. Describe the safety/toxicity profile of the treatment regimen and the overall risk for this patient.

l. Was this treatment regimen recommended by another specialist(s) in Ontario?

- NO
- Yes, recommended by a Multi-Disciplinary Cancer Conference or equivalent collaborative meeting
- Yes, recommended by a specialist that has seen and assessed the patient.
- Other, specify:

m. If the requested drug is NOT approved, what is the treatment plan for this patient?

n. Provide any additional information to support your rationale for seeking funding from the Case-by-Case Review Program.

Section 6: Checklist of Supporting Documentation ¹

In the list below, indicate the documentation included in your request package. Please upload these files into CCO's secure upload tool when submitting your application.

	Types of Documentation	Included?
1.	Published evidence demonstrating the clinical benefit (e.g., survival) and tolerability of the treatment regimen. <i>Failure to provide full text articles will delay the review of your request.</i>	<input type="checkbox"/> Yes - Required
2.	Consult notes in patient's health record that informed the treatment plan (e.g. transplant, surgical, radiation, multi-disciplinary consult notes)	<input type="checkbox"/> Yes - Required
3.	Clinic notes from the last two clinic visits that describe: a) patient's current status and symptoms b) prior therapies attempted and response c) rationale for omitting other potential interventions	<input type="checkbox"/> Yes - Required
4.	Labwork (e.g., CBC, chemistry, tumour markers) from the last two clinic visits and any other labwork that inform the treatment plan.	<input type="checkbox"/> Yes - Required
5.	Pathology report	<input type="checkbox"/> Yes <input type="checkbox"/> N/A
6.	Bone marrow biopsy / Aspirate	<input type="checkbox"/> Yes <input type="checkbox"/> N/A
7.	Imaging (e.g., CT scan) reports for the last two scans .	<input type="checkbox"/> Yes <input type="checkbox"/> N/A
8.	Approval letter from the Special Access Programme (for drugs not approved for sale in Canada)	<input type="checkbox"/> Yes <input type="checkbox"/> N/A
9.	Cytogenetic/Molecular Marker Testing	<input type="checkbox"/> Yes <input type="checkbox"/> N/A
10.	Decision letters from public drug funding programs (e.g., Exceptional Access Program) or patient assistance programs that previously assessed this request for funding.	<input type="checkbox"/> Yes <input type="checkbox"/> N/A

¹ Note: CCO may request additional information, as necessary, in order to review your funding request.

Consents and Approvals

By checking this box, I confirm that the patient named above, or relevant substitute decision-maker where applicable, has been informed by the Applicant that the patient's Personal Health Information (PHI), as such term is defined in the *Personal Health Information Protection Act, 2004*, as amended, will be disclosed to and used by Cancer Care Ontario (CCO) in order to

determine the patient's eligibility to receive funding for specific cancer drugs pursuant to the eligibility criteria as set out in the Case-by-Case Review Program. In order to determine eligibility for a specific drug, it may be necessary for CCO to disclose the patient's PHI to other administrative programs for health services and insured benefits at Ministry of Health and Long-Term Care, as well as the patient's treating pharmacist.

By checking this box, I confirm that the patient, or relevant substitute decision-maker where applicable, has provided his/her express consent for the disclosure and use of their PHI in accordance with the above stated purpose.

By checking this box, I certify that the information set out in this Request Form is true and accurate, to the best of my knowledge.

Date Completed

Please upload this Request Form and all supporting documentation via CCO's secure link: <http://www.cancercare.on.ca/cbcrp>. To avoid unnecessary delays in processing, ensure that the Request Form is complete and that all relevant documentation is provided.

Should you have any questions about the Request Form or this program, please contact CBCRP at cbcrp@cancercare.on.ca.