Ontario Health
Cancer Care Ontario

Print Form

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

This form is for **NEW REQUESTS** and should be completed before the first dose of the requested drug is dispensed.

Notes:

- **The CBCRP does not provide retroactive funding. Please submit this form and all required documents at least two weeks in advance of treatment initiation.**
- Requests for take-home cancer drugs (e.g. oral chemotherapy) are accepted but patients must have coverage under the Ontario Drug Benefit Program to be reimbursed (if approved).
- Requests for funding under the CBCRP are adjudicated against the eligibility criteria set forth in the *Case-by-Case Review Policy for Cancer Drugs*.

Collection and Use of Personal Information:
Ontario Health (OH) collects and uses information on this form to make eligibility recommendations; and for the purpose of analysis or compiling statistical information with respect to the management of, evaluation or monitoring of, the allocation of resources to or planning for all or part of the health system, including the delivery of services, pursuant to section 45 of the *Personal Health Information Protection Act*, 2004.

As part of the evaluation and reimbursement process for CBCRP, it may be necessary for OH to disclose or share the patient's personal health information to other administrative programs for health services and insured benefits at the Ministry of Health or at OH.

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 https://www.cadth.ca/pcodr/find-a-review.)

Section 1: Applicant Information

Treating Oncologist

First Name | Last Name | CPSO No.

Telephone | Fax | Email

Affiliated Hospital /Cancer Centre

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 | Last Name

Telephone | Fax | Email

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Section 2: Patient Information

First Name | Last Name

Date of Birth (MM/DD/YY) | OHIN

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	Treatment Response *Specify: adequate/inadequate response; stopped due to unacceptable toxicity, disease progression or other reason*

Section 4: Treatment Regimen

a. Requested Drug(s): Generic Name | Brand Name

b. DIN (s) | c. Dosage Form ◯ IV ◯ SC ◯ PO ◯ Other, specify

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.

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

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

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

Source	Outcome	
☐ Exceptional Access Program	◯ Rejected	◯ Re-directed to CBCRP
☐ New Drug Funding Program	◯ Rejected	◯ Re-directed to CBCRP
☐ Manufacturer's Program (e.g., Patient Assistance Program)	◯ Rejected	◯ Partial Coverage
☐ Hospital Budget	◯ 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)

g. Please explain the expected benefits of requested therapy compared to **best supportive care** with respect to survival and quality of life.

h. 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:

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

j. 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)*

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

- ◯ NO
- ◯ YES, specify:

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

m. 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:

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

o. 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 via eClaims when submitting your application.

	Types of Documentation	Included?	
1.	Published evidence demonstrating the clinical benefit (e.g., survival) and tolerability of the treatment regimen. *Failure to provide full text articles will delay the review of your request.*	☐ Yes - Required	
2.	Consult notes in patient's health record that informed the treatment plan (e.g. transplant, surgical, radiation, multi-disciplinary consult notes).	☐ 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	☐ 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.	☐ Yes - Required	
5.	Pathology report	☐ Yes	☐ N/A
6.	Bone marrow biopsy / Aspirate	☐ Yes	☐ N/A
7.	Imaging (e.g., CT scan) reports for the last **two scans.**	☐ Yes	☐ N/A
8.	Approval letter from the Special Access Programme (for drugs not approved for sale in Canada).	☐ Yes	☐ N/A
9.	Cytogenetic/Molecular Marker Testing	☐ Yes	☐ 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.	☐ Yes	☐ N/A

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

Section 7: Consents and Approvals

☐ 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.

☐ 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 the patient's PHI in accordance with the above stated purpose.

Please complete this section, if you are a **physicians from outside of Ontario** (i.e., Quebec or Manitoba).

☐ By checking this box, I confirm that the patient named above, or relevant substitute decision-maker where applicable, consents that the patient's personal health information will be collected and used by OH in order to determine the patient's eligibility to receive drug reimbursement as well as for purposes for analysis or compiling statistical information with respect to the management of, evaluation or monitoring of, the allocation of resources to or planning for all or part to the health system, including the delivery of services.

To determine eligibility for a specific drug, it may be necessary for OH to disclose the patient's PHI to other administrative programs for health services and insured benefits at the Ministry of Health as well as the patient's treating pharmacist.

Date Completed

Section 8: How to submit an application

- Submit this Request Form and all required documentation via eClaims:
  See "Application Instructions" at https://www.cancercareontario.ca/en/Funding/Case-by-Case_Review_Program

- To avoid unnecessary delays in the review of your application, please ensure that this Request Form is complete and that all relevant documentation is provided.

- The CBCRP aims to provide a decision within two weeks from a complete application.

- For complete application instructions and program policies, visit the CBCRP website.

Should you have any questions about the Request Form or this program, please email CBCRP at: OH-CCO_cbcrp@ontariohealth.ca.

Ontario Health