

GUIDING PRINCIPLES OF THE COMPASSIONATE ACCESS PROGRAM APPLICATION PROCESS

PREAMBLE

The Compassionate Access Program (CAP) application process is intended to address the goals of the [BCCA Systemic Therapy Treatment Policy Number III-40](#) to support flexibility in access to evidence-based treatments that are indicated in unusual or exceptional clinical circumstances or are under review for formal implementation. Approval is on a **case-by-case basis** and requires Tumour Group and Systemic Therapy Program agreement that the requested therapy meets these goals and that oncology drug funding will be provided by BCCA. Approval for one case does not imply approval for others. Approvals must be obtained prior to the patient being booked to receive the drug therapy.

The Compassionate Access Program process aims to:

- ensure optimal patient care and safety in the administration of chemotherapy agents
- ensure that drug treatment choices are evidence-based
- ensure fiscal responsibility in utilizing the Provincial Oncology Drug Budget
- maintain the integrity of the Provincial Systemic Therapy drug database

WHEN A CAP APPLICATION IS REQUIRED

- a. A BCCA protocol with the '**U**' designation and eligibility criteria, which stipulates requirement for CAP approval.
 - b. **No BCCA protocol** is available for a proposed treatment.
 - c. Drug(s) **not on the BCCA Drug Benefit List**
 - d. **Changes to an existing BCCA treatment protocol** including:
 - substitution of different drugs
 - use of different doses or routes
 - extensions to number of cycles/duration
 - expansions to eligibility criteria/indication
 - e. **Class II** drug(s) being used
 - as a single agent in an indication for which no BCCA protocol exists, or
 - in combination with other agents for which no BCCA protocol exists, or
 - in a manner that does not fit the specific indications and eligibility listed in BCCA protocols and on the Class II form
 - f. **Class I** drug(s) being used:
 - in combination with radiation for which no BCCA protocol exists
 - in any circumstance where there is no Tumour Group specific palliative protocol of optimal therapies that outlines dosage guidelines for the specific drug(s) as single agents or in combination
- It is up to the prescribing physician to provide literature support for the proposed treatment when a request is made. In the absence of this, the Tumour Group Designate who authorizes the approval of such therapy can provide the reference.

RECURRING APPLICATION

If a Tumour Group routinely (more than 5 times) accesses a treatment through the CAP process for a specific indication that falls into any of the above categories, they will be requested to develop:

- a formal PEC proposal; or
- Treatment Policy, Protocol, Provincial Pre-Printed Order AND Protocol Specific Patient Hand-Out.

The Systemic Therapy Program has the right to decline further funding if this requirement is not fulfilled within a reasonable time frame.

OUTCOMES

The Systemic Therapy Program will periodically request follow-up data on the outcomes of Compassionate Access therapies.

- Further literature/presentation evidence
- Benefits in BC patients given access to the drug/drugs

CLINICAL TRIALS

Principal Investigators of clinical trials that include a treatment arm requiring Compassionate Access approval should seek pre-approval for all trial participants from the Systemic Therapy Program prior to activating the trial, so that the requirement for CAP submission may be waived.