

British Columbia Cancer Agency | POLICY

Title: Systemic Therapy Treatments		Number: III-40
Effective Date: 27 January 2000	Approved By: Provincial Systemic Program Committee	
Revised Date: 1 February 2012		

Page 1 of 7

Definitions

Approved treatment protocol:

- a document whose content has been approved by the Provincial Systemic Therapy Program and which describes systemic treatment of cancer in detail, including:
 - unique protocol code
 - indications and objectives of treatment, consistent with BCCA Cancer Management Manual
 - eligibility and exclusion criteria
 - treatment plan summary
 - treatment program (e.g. dose, schedule, modifications, etcetera)
 - required baseline and ongoing clinical and laboratory monitoring
 - potential toxicity and response
 - supportive care recommendations
 - other relevant instructions to ensure safe and effective delivery of the treatment.

Approved clinical trial protocol (also known as "study protocol"):

- a treatment protocol which has been approved by Provincial and Regional Site teams, BCCA Clinical Investigations Committee, relevant regional systemic therapy and research processes and ethics authority and which describes the use of a medication or regimen which is undergoing evaluation in a group of consenting patients.

Benefit drugs:

- medications whose cost for treatment of registered patients is borne, province-wide, by BCCA (4 possible classifications):

Class I: used in the active treatment of cancer or for a specific purpose, which is defined in an approved treatment protocol

Class II: used in the active treatment of cancer or for a specific purpose which is defined in an approved treatment protocol but for which certain conditions of use must be met and additional information provided

Restricted funding: used in the active treatment of cancer in a specific patient, after approval to use [has been obtained from the BCCA Compassionate Access Program](#).

Clinical trial: used in the active treatment of cancer and part of an approved clinical trial protocol but not provided by sponsor; may include drugs published on the Benefit Drug List and/or those used for non-marketed indications

British Columbia Cancer Agency | POLICY

Title: Systemic Therapy Treatments		Number: III-40
Effective Date: 27 January 2000	Approved By: Provincial Systemic Program Committee	
Revised Date: 1 February 2012		

Page 2 of 7

Registered patient:

- a patient who has met the criteria for eligibility for drug reimbursement and for whom essential identifying information has been entered into the Cancer Agency Patient Information System

POLICY:

To promote safe, evidence-based and cost-effective management of cancer throughout British Columbia, systemic therapy will be restricted to the use of approved treatment protocols (Class I or II), approved clinical trial protocols, or approved restricted funding or exceptional indication systemic therapy treatments, all of which must be endorsed by the relevant Provincial Tumour Group(s) and approved by the Provincial Systemic Therapy Program.

The cost of benefit drugs will be borne by BCCA for treatment of registered patients and will be reimbursed to the treating facility upon submission of a reimbursement claim by the treating facility to BCCA's CON program. Reimbursement for the cost of non-benefit drugs will be denied.

A. [Procedures for development and maintenance of standard systemic treatment protocols](#)

1. The individual proposing a systemic treatment will:
 - develop a written treatment protocol which incorporates the components listed in the above definition of a treatment protocol
 - obtain endorsement of the protocol from the relevant Provincial Tumour Group
2. The Provincial Tumour Groups will:
 - ensure that written treatment protocols which reflect currently recommended systemic therapy of cancer are developed, approved and maintained
 - ensure that delivery of proposed treatment protocols is feasible and that information necessary (Appendix I) to deliver the treatment is developed
 - review proposed treatment protocols and submit them to the Priorities and Evaluation Committee and to the Systemic Therapy Program Analyst for resource impact analysis and presentation to the Systemic Therapy Program
 - *Note: the Provincial Systemic Therapy Program Committee meets on the last Thursday of each month; proposals must reach the Systemic Therapy Program Analyst no less than two weeks prior to a meeting to be included on the agenda.*
 - encourage and facilitate Province-wide adherence to approved treatment protocols

British Columbia Cancer Agency | POLICY

Title: Systemic Therapy Treatments		Number: III-40
Effective Date: 27 January 2000	Approved By: Provincial Systemic Program Committee	
Revised Date: 1 February 2012		

Page 3 of 7

3. The Systemic Therapy Program Analyst will initiate and meet with an *ad hoc* "Resource Group", consisting of representatives from the Systemic Therapy Program, Medical Oncology, Pharmacy, Nursing and/or other relevant groups, to discuss the Regional and Provincial resource impact of the proposed protocol. The Resource Group's comments will be provided to the Provincial Systemic Therapy Program.
4. The Provincial Systemic Therapy Program Committee will:
 - evaluate proposed treatment protocols and the comments of the "Resource Group"
 - where deemed necessary, due to resource implications, forward the protocol to the Priorities and Evaluation Committee for their assessment
 - communicate decision (or progress, if decision is delayed) to the Tumour Group and relevant Agency personnel within two weeks of the proposal being discussed
 - approve other informational documents related to the protocol, as required
 - grant final approval when all necessary information related to the protocol is available
 - determine the effective date, any restrictions or conditions that may apply to the approval and review date (if necessary to assess restricted or conditional use)
 - ensure that adherence to restrictions or conditions is reviewed on the pre-determined review date
 - ensure that all approved protocols and related information are maintained, distributed appropriately, and regularly reviewed
 - encourage and facilitate Province-wide adherence to approved treatment protocols
5. The Provincial Drug Information Coordinator, guided by and in collaboration with the Systemic Therapy Protocol Database Committee, will:
 - ensure that approved systemic therapy treatment protocols and related documents (Appendix I) have been developed according to established standards and approved by the relevant group(s)
 - ensure that the most recently updated protocols and related documents are available and/or distributed to the relevant Regional and Communities Oncology Network personnel by the effective date and published in the next "*Systemic Therapy Update*".

British Columbia Cancer Agency | POLICY

Title: Systemic Therapy Treatments		Number: III-40
Effective Date: 27 January 2000	Approved By: Provincial Systemic Program Committee	
Revised Date: 1 February 2012		

Page 4 of 7

B. [Procedures for obtaining approval of clinical trials protocols](#)

Principal Investigators are referred to the Systemic Therapy Policy "Clinical Trials" for details of submission requirements.

1. The Principal Investigator(s) (PI) will present the proposed clinical trial protocol to the relevant Provincial Tumour group and, if appropriate, to the Regional Tumour Site Team and/or Regional Medical or Radiation Oncology Team for review and approval.
2. Upon approval by the Provincial Tumour Group and Site Team, the Principal Investigator will submit the proposed protocol to the BCCA Clinical Investigations Committee, the relevant regional processes at each participating Centre and to their local ethics committee for review and approval.
3. The Clinical Investigations Committee will review the proposed protocol for its scientific value, ethical implications and patient consent form, and will communicate the Committee's decision to the Principal Investigator, with requests for modifications to the protocol if deemed necessary.
4. The regional processes will review the proposed protocol for resource impact and feasibility in their Centre and will communicate their decision to the Principal Investigator, with an intended implementation date.
5. Designated individuals at each participating Centre (e.g. Clinical Trial Nurse, Health Records Administrator, Clinical Trials Pharmacist, etc.), in collaboration with each other, their regional processes and the Centre's Principal Investigator, will ensure that all resources, information and procedures necessary for their discipline to deliver the clinical trial are established by the projected implementation date and maintained throughout the trial.
6. The Principal Investigator at each Centre will ensure that all requirements of a clinical trial protocol under their direction are adhered to at all times.

British Columbia Cancer Agency | POLICY

Title: Systemic Therapy Treatments		Number: III-40
Effective Date: 27 January 2000	Approved By: Provincial Systemic Program Committee	
Revised Date: 1 February 2012		

Page 5 of 7

C. [Procedures to obtain approval for Restricted Funding benefit drugs and exceptional use of drugs](#)

[See Systemic Therapy Policy III-45 for Compassionate Access Program.](#)

References:

Systemic Therapy Program Team Charter, 1998

Systemic Therapy Program Flow Chart: "Provincial Policy Change", 1998

Old BCCA Policies:

III-100: "Drug Benefit List", June 28, 1991

III-140: "Formulary Introduction", March 1, 1991

III-150: "Addition of a drug to the formulary", March 1, 1991

Report of Pharmacy Task Force, July, 1997

Clinical Investigations Committee, Guidelines for submission of protocols, Feb/98

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APPENDIX I: INFORMATION DOCUMENTS RELEVANT TO DELIVERY OF STANDARD TREATMENT PROTOCOLS

Document	Definition	Developed and maintained by:	Approved by:	Review Interval
protocol summary	- description of systemic treatment of a specific cancer	Tumour Group	PSTP	- in response to change to protocol or practice
pre-printed orders (PPO)	- template for delivery of a treatment protocol	Provincial PPO teams	Provincial PPO teams	- in response to change to protocol or practice
protocol patient information	- overview of systemic treatment of a specific cancer	Tumour Group	PSTP	- in response to change to protocol or practice
drug monograph	- information on drug(s) in protocol, for health care professionals	Cancer Drug Manual process	Cancer Drug Manual Editorial Board	- every 4 years or in response to crucial new drug information
patient drug information	- information on drug(s) in protocol, for patients	Cancer Drug Manual process	Cancer Drug Manual Editorial Board	- every 4 years or in response to change in information
Pharmacy directives	- instructions for Pharmacy staff, where necessary	Tumour Group Pharmacist and Regional Site Team Pharmacists	Provincial Pharmacy Professional Practice Council	- every 4 years or in response to change in protocol or practice
Nursing procedures	- instructions for Nursing staff, where necessary	Tumour Group Nurse and Regional Site Team Nurses	Nursing Practice Committee	- every 4 years or in response to change in protocol or practice
Benefit Drug List	- list of drugs for the active treatment of cancer, whose cost is borne province-wide by BCCA	PDIC, in response to PSTP decisions	PSTP	- annually, by Provincial Pharmacy Professional Practice Council
Class II Drug Registration Form	- document required to ensure coverage of Class II drug cost	PDIC, in response to PSTP decisions	PSTP	- annually, by Provincial Pharmacy Professional Practice Council

¹files are in *h:\everyone\systemic\chemo*

Tumour Group = Provincial Tumour Groups will be inter-disciplinary, with membership representative of all those associated with the patient care process for the particular tumour site

PDIC = Provincial Drug Information Coordinator, who ensures that documents are prepared according to established standards and approved by the relevant group(s)

PSTP = Provincial Systemic Therapy Program

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