# SYSTEMIC THERAPY TREATMENTS POLICY (III-40)

## Summary of Changes

<table>
<thead>
<tr>
<th>Institution name and logo</th>
<th>NEW</th>
<th>Previous</th>
</tr>
</thead>
<tbody>
<tr>
<td>BC Cancer</td>
<td>BC Cancer</td>
<td>BCCA</td>
</tr>
<tr>
<td>Purpose</td>
<td>Class I or restricted</td>
<td>Class I or II, or restricted</td>
</tr>
<tr>
<td>Appendix I - renewal interval for patient drug information and drug monographs</td>
<td>in response to change to protocol or practice</td>
<td>every 4 years or in response to crucial new drug information</td>
</tr>
</tbody>
</table>

| Appendix II               | Updated                 |                        |
1. Introduction
   1.1. Purpose

   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 restricted), approved clinical trial protocols, or approved 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.

   1.2. Scope

2. Policy
   2.1. Policy Statement #1

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

3. Responsibilities and Compliance
   3.1. Responsibilities

   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:
   • Priorities and Evaluation Committee and to the Business Affairs Director for resource
     impact analysis and presentation to the Systemic Therapy Program
   • Interim Therapeutics Evaluation Committee (H:\Systemic\ITEC COMMITTEE) if the
     treatment involves only drugs already on the Benefit List and of limited impact on:
     • drug budget
     • staff resources
   • encourage and facilitate Province-wide adherence to approved treatment protocols

   Released: 01/May/2019
   Next Review: To be determined

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   organization not associated with PHSA. A printed copy of this document may not reflect the current electronic version on the PHSA Intranet.
3. The Provincial Systemic Therapy Program Committee will:
   - evaluate proposed treatment protocols to ensure that they are safe, evidence-based and cost-effective, while considering the needs of the patients and healthcare professionals, as well as the need to avoid product duplication
   - communicate decision (or progress, if decision is delayed) to the Tumour Group and relevant Agency personnel 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

4. The Provincial Drug Information Coordinator 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".

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.

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.

3.2. Compliance

4. Related Documents

Systemic Therapy Policy III-45 for Compassionate Access Program.
5. 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 BC Cancer Management Guidelines
  - 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, BC Cancer 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 BC Cancer (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

  **Restricted funding**: used in the active treatment of cancer in a specific patient, after approval to use has been obtained from the BC Cancer 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

  **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
6. References

Systemic Therapy Program Team Charter, 1998
Old BC Cancer Policies:
   III-140: "Formulary Introduction", March 1, 1991
   III-150: "Addition of a drug to the formulary", March 1, 1991
Clinical Investigations Committee. Guidelines for submission of protocols, Feb/98
## 7. Appendices

### Appendix I: information documents relevant to delivery of standard treatment Protocols

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

1. Files 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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Appendix II: Funding review process for new Systemic Therapy Programs

- **pCODR** Review and recommendation
- **pCPA** National contract negotiation
- **CDOAC** Implementation considerations
  - **PEC** Semi-annual review (Fall, Spring)
  - Out-of-cycle review of proposals with clinically important improvement (implement once resources in place)
  - **iTEC** Reviews every 2 months of proposals outside PEC scope
- **Tumour Groups** Request for new treatment programs
- **PSTP** Pharmacoeconomics Pharmacist
  - Economic model
  - Budget impact
- **PTSC** Monthly meeting
  - Drug cost and resources impact
  - Implementation plan
- **BCCSS** Provincial contract negotiation
- **BC Cancer Executive** Compilation of drug budget to PHSA Executive & BC Ministry of Health

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**PSTP** = Provincial Systemic Therapy Program  
**PSTC** = Provincial Systemic Therapy Committee  
**PEC** = Priorities & Evaluation Committee  
**iTEC** = Interim Therapeutic Evaluation Committee  
**pCODR** = pan-Canadian Oncology Drug Review  
**pCPA** = pan-Canadian Pricing Alliance  
**BCCSS** = BC Clinical and Corporate Support Services

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**Last page of document**

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| | Helen Anderson | Systemic Therapy Leader | 28-Feb-2019 |
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| | Unknown | Provincial Systemic Therapy Program |
| Owner(s): | Unknown | Provincial Systemic Therapy Program |
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