Understanding BC Cancer Agency Chemotherapy Protocols

Contents

Introduction ............................................................................................................................................... 2
Purpose of Protocol Codes .................................................................................................................. 3
  Patient Safety ...................................................................................................................................... 3
  Evidence-based Treatment ............................................................................................................... 3
  Accountability ................................................................................................................................. 3
Protocol Code Format .......................................................................................................................... 3
Absence of a Protocol Code ............................................................................................................... 5
Absence of a Treatment Protocol ...................................................................................................... 6
Benefit Status ...................................................................................................................................... 6
Class I Drugs ...................................................................................................................................... 7
Class II Drugs ...................................................................................................................................... 8
Compassionate Access Program (CAP) Drugs .................................................................................. 8
Special Access Program (SAP) .......................................................................................................... 8
Introduction

In order to provide safe, evidence-based, and cost-effective cancer treatment to all cancer patients in B.C., the BC Cancer Agency has developed cancer treatment regimens or chemotherapy protocols. There are more than 350 different protocols approved for use by the BC Cancer Agency. Summaries of these protocols can be found on the BC Cancer Agency website (www.bccancer.bc.ca) under Chemotherapy Protocols.

Each protocol summary contains the following information:

- Protocol code
- Tumour group
- Eligibility and exclusion criteria
- Tests (baseline tests and ongoing clinical and laboratory monitoring)
- Premedications
- Treatment (including drug(s), dose, route of administration, length and number of cycles)
- Dose modifications (potential toxicities and response)
- Precautions
- BC Cancer Agency contact physician
- Date of last revision
- References

It is important to note that the Provincial Systemic Therapy Program of the BC Cancer Agency reviews and revises these protocols on a periodic basis and that both the format and content of the protocols may change. Therefore, printed copies of protocols should not be stored for future reference, as they may soon be out of date. The last revision date is shown at the end of each protocol summary. Always check the BC Cancer Agency website for the most recent information.
Purpose of Protocol Codes

Patient Safety

The unique protocol code allows accurate communication within the health care team to readily identify the treatment prescribed for a patient. This is important given that chemotherapy often involves complex dosing schedules of drugs with potentially severe toxicities. In addition, the BC Cancer Agency chemotherapy protocols have corresponding BC Cancer Agency preprinted orders (PPO’s) and patient information handouts. Use of the protocol codes assist other members of the health care team involved in chemotherapy delivery to have the necessary information to perform clinical checks and provide the safest possible patient care.

Evidence-based Treatment

The BC Cancer Agency chemotherapy protocols have been developed based on the latest evidence related to management of specific cancers. By capturing BC Cancer Agency protocol information, the BC Cancer Agency is able to track outcome data for specific patient populations treated with specific protocols in BC. This information further informs clinicians regarding treatment efficacy.

Accountability

BC Cancer Agency protocol data is also used to obtain valuable information for monitoring and forecasting related to drug therapy usage with the intent of making evidence-based drug therapies available for BC residents through effective management of the oncology drug budget.

Protocol Code Format

Each protocol is assigned a specific code, which is formatted as follows:

- The first two letters indicate the tumour group (see Table 1).
- If a tumour group has more than one site, the tumour site may be included. For example, ovarian cancer protocol codes begin with GOOV (“GO” for gynecology tumour group, “OV” for ovarian cancer).
- The protocol code may identify if the treatment is adjuvant (AJ) or
advanced (AV). In general:
  - Adjuvant treatment is given after curative treatment (radiation or surgery) to reduce risk of disease recurrence and improve survival.
  - Advanced treatment intent is palliative and generally used to control progression or symptoms of metastatic or unresectable disease.
- The first one to three letters of the drug(s) used in the protocol usually complete the protocol code.
- Some Class I drugs do not have BC Cancer Agency protocols associated with them or may be used as single agent treatment. These drugs are indicated on the 
  * Benefit Drug List* [Systemic Therapy - Reimbursement & Forms] by the default code “NOS” which stands for “Not Otherwise Specified”. The order will be assigned a protocol code following the format XXNOS where the XX is substituted with the tumour site being treated.

<table>
<thead>
<tr>
<th>Table 1: Tumour Group Abbreviations</th>
</tr>
</thead>
<tbody>
<tr>
<td>BR</td>
</tr>
<tr>
<td>BMT</td>
</tr>
<tr>
<td>CN</td>
</tr>
<tr>
<td>CML</td>
</tr>
<tr>
<td>GI</td>
</tr>
<tr>
<td>GU</td>
</tr>
<tr>
<td>GO</td>
</tr>
<tr>
<td>HN</td>
</tr>
<tr>
<td>KS</td>
</tr>
<tr>
<td>LK</td>
</tr>
</tbody>
</table>

* U is for “undesignated” and is added before the tumour group abbreviation to indicate that the protocol requires case-by-case approval for funding through the Compassionate Access Program (CAP).

Example:

The BC Cancer Agency Protocol Summary for Adjuvant Therapy for Breast Cancer using DOXOrubicin and Cyclophosphamide has the protocol code BRAJAC. This indicates that it is a breast cancer protocol involving adjuvant therapy using ADRIAMYCIN® (DOXOrubicin) and cyclophosphamide.
Every attempt is made to have protocols follow this general pattern, but there are variations:

- Not every protocol code identifies the intent of treatment (i.e., whether it is “adjuvant” or “advanced”).
- Most protocol codes use generic drug names, but occasionally brand names are used instead (e.g., ADRIAMYCIN® in BRAJAC).
- A number of protocol codes do not follow the BC Cancer Agency format for nomenclature but have been adopted because the acronyms were widely used and predated BC Cancer Agency protocols.

More examples:

- LUMMPG is a lung protocol for malignant mesothelioma using platinum (CISplatin) and gemcitabine.
- BRAVANAS is a breast protocol for advanced disease using anastrozole.
- LYHDMTXP is a lymphoma protocol using high-dose methotrexate (MTX), for the treatment of primary intracerebral lymphoma.
- GIFOLFIRI is a gastrointestinal protocol using folinic acid, fluorouracil, and irinotecan.
- UGUPCABA is a genitourinary prostate protocol using cabazitaxel and predniSONE and requiring case-by-case approval prior to treatment.
- LKNOS is the protocol code used for hydroxyurea treatment for any leukemia. There is no specific protocol for hydroxyurea for any tumour group.

When a chemotherapy order is written, a specific protocol code must accompany the order to allow the pharmacist to check the written order. It is important to check that the protocol ordered is consistent with the patient’s diagnosis and eligibility criteria. If it is not, the pharmacist must contact the ordering physician to clarify any discrepancies.

Absence of a Protocol Code

When the protocol code is absent from the orders, the pharmacist should follow the guidelines below to obtain this essential information:

- If this is the patient’s first treatment, contact the ordering physician to confirm which BC Cancer Agency approved protocol is being used for treatment. Ensure that the patient’s diagnosis is consistent with the assigned protocol by following the eligibility criteria outlined in the.
protocol.

- If the patient has been previously treated, check that the current orders are consistent with the previous protocol. The protocol code for the previous cycle can then be assigned to the chemotherapy orders, and the pharmacist should follow the previous protocol for checking the chemotherapy orders.

Absence of a Treatment Protocol

There are three possible sources of protocol codes:

1. CAP outcomes
2. Chemotherapy Protocols
3. the Benefit Drug List [Systemic Therapy - Reimbursement & Forms]

When an XXNOS or CAP-assigned protocol code is used, there is no protocol to guide checking the chemotherapy order for eligibility, dosing, and appropriateness of treatment. It must be determined whether the treatment is suitable for the patient from other sources of information. These include:

- Cancer Management Guidelines
- Other chemotherapy regimen resources
- Literature support for proposed treatment
- CAP-assigned protocols sometimes refer to another protocol that can be used for guidance

Benefit Status

The BC Cancer Agency pays for the cost of all approved cancer treatment medications for all residents of BC. Supportive care medications are not covered by the BC Cancer Agency. When a patient is diagnosed with cancer, the physician must register the patient with the BC Cancer Agency. At that time, a 7-digit BC Cancer Agency Identity Number will be issued and used to identify and track all activity related to that patient. The first two numbers in the BC Cancer Agency number represent the year in which the patient was first registered with the BC Cancer Agency (i.e., BC Cancer Agency # 14-12345 indicates that the patient was registered in 2014).
The BC Cancer Agency will reimburse to the dispensing hospital pharmacy the drug costs associated with all approved cancer treatments for registered patients in the province. These approved drugs are referred to as “benefit drugs” and are eligible for reimbursement through the Communities Oncology Network (CON) Program on an individual billing basis or directly if the drugs are administered in a BC Cancer Agency Centre. CON hospitals submit claims to BC Cancer Agency through a program called OSCAR (Online System for Cancer drug Adjudication and Reimbursement). All benefit drugs, and their indications for use, are listed in the BC Cancer Agency Benefit Drug List [Systemic Therapy - Reimbursement & Forms].

The Benefit Drug List is frequently revised; therefore, it is advisable to review this list directly from the BC Cancer Agency website. Benefit drugs are divided into two general categories: Class I and Restricted Funding (R) drugs that require case-by-case approval from the Compassionate Access Program (CAP approval). Occasionally patients may also be approved to receive cancer treatments with drugs otherwise not available in Canada through Health Canada’s Special Access Program (SAP).

Class I Drugs

A drug designated as Class I is used in the active treatment of cancer or for a specific purpose which is defined in an approved BC Cancer Agency treatment protocol. Some Class I drugs may be used as a single agent for a treatment not included in an approved BC Cancer Agency protocol. These drugs are indicated in the Benefit Drug List [Systemic Therapy - Reimbursement & Forms] with a NOS (not otherwise specified) default protocol code. A limited number of Class I drugs do not have any BC Cancer Agency protocols associated with their use (e.g., hydroxyurea). These are also indicated on the Benefit Drug List with a NOS default code.

If a default NOS protocol code is not included on the Benefit Drug List, the drug must be used following an approved treatment protocol or the treatment approved by the Compassionate Access Program (see below). There are restrictions on the approved indications for some drugs. For example, megestrol acetate is covered for the active treatment of breast and endometrial cancers, but is not covered for appetite stimulation or symptom management.

Approved drug indications, doses and treatment guidelines are determined by the Tumour Groups at the BC Cancer Agency using evidence-based and best practice standards. Tumour groups are interdisciplinary teams that specialize in treating one cancer site, such as the Breast Tumour Group. Members of the
individual Tumour Groups can be contacted for questions and concerns regarding protocols. Membership lists are located under each tumour site in Cancer Management Guidelines on the BC Cancer Agency website.

Class II Drugs

All drugs have been delisted from Class II as of October 1, 2016. Previously, this was a designation for drugs that did not require undesignated approval but were restricted for use for specific indications only.

Compassionate Access Program (CAP) Drugs

Case-by-case approval can be granted for the use of a drug that does not fit into the Class I criteria, or for which there is no approved BC Cancer Agency protocol. Policy III-45 – Compassionate Access Program [Systemic Therapy - Policies & Procedures] outlines the process of the BC Cancer Agency Compassionate Access Program (CAP). Compassionate Access Program (CAP) approval can be obtained by providing the appropriate patient-specific clinical information to the Provincial Systemic Therapy Program. CAP requests are submitted online through the secure Compassionate Access Program website. This website may also be consulted to determine whether a treatment regimen has been approved for a patient. New users must register with the CAP office to gain access to the system (email cap_bcca@bccancer.bc.ca).

To be eligible for reimbursement, notification of approval must be received prior to scheduling patients for treatment. In some cases, approval is granted for a specific number of cycles, after which the patient’s response to treatment must be reassessed. If treatment is to continue, a second CAP request must be submitted to the Provincial Systemic Therapy Program.

Special Access Program (SAP)

Health Canada’s Special Access Program (SAP) provides practitioners with access to non-marketed drugs for the treatment of patients with serious or life-threatening conditions when conventional therapies have failed, are unsuitable, or are unavailable. The SAP authorizes a manufacturer to sell a specific quantity of drug that cannot otherwise be sold or distributed in Canada. The Drugs with Special Ordering Procedures [Systemic Therapy - Reimbursement & Forms] document on the BC Cancer Agency website lists drugs used for cancer.
treatment that require application to the SAP program. The document also contains useful information about procedures for obtaining these drugs. A link to the SAP’s drug request form (SAP Request Form) is also available.

When a request is made for a SAP drug to be used in cancer treatment, the pharmacist should first determine the benefit status of the drug:

- If the drug is a Class I drug and is being used for an approved indication and dosage, the order can be processed, and the SAP procedure can be implemented.
- If the drug is being used for an indication that requires CAP approval, prior approval must be received from the Provincial Systemic Therapy Program before ordering the drug.

The cost of each SAP drug may be paid by the manufacturer or by the BC Cancer Agency; each drug is handled individually. If reimbursement is to come from the BC Cancer Agency, all necessary documentation must be completed prior to obtaining and dispensing the drug.