



BC Cancer Agency

Systemic Therapy Update

Volume 7, Number 4

for health professionals who care for cancer patients April 2004

Website access at <http://www.bccancer.bc.ca/STUpdate/>

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FAX request form and IN TOUCH phone list are provided if additional information is needed.

CHANGE TO REIMBURSEMENT PROCEDURES FOR BC CANCER AGENCY BENEFIT DRUGS

We wish to inform you of an important change to the reimbursement procedures for oncology benefit drugs by the BC Cancer Agency. The BC Cancer Agency (BCCA), a member organisation of the Provincial Health Services Authority (PHSA), is responsible for funding drug therapies, according to its policy guidelines, for the treatment of cancer patients. BCCA reimburses the Communities Oncology Network (CON) Pharmacies for the actual acquisition cost of benefit drugs up to the maximum price as determined by the BCCA contract price.

PHSA has selected Medbuy as its Group Purchasing Organisation effective November 2003. PHSA will be honouring contracts, which were active as of that date. In order to sustain the best contract prices for oncology drugs and manage the provincial oncology drug budget, it is required that, effective **April 1, 2004**, all BCCA reimbursable drugs which are not on a continuing BCHS/HealthPRO contract be purchased from the Medbuy contract. Any existing inventories will be reimbursed at the BCCA contract price at the time of acquisition. Subsequent purchases must be made through this new process and will be **cost neutral** to the Regional Health Authorities.

Procedures have been set in place to allow all CON hospitals in BC, regardless of GPO membership, to purchase oncology drugs at the Medbuy contract price. Orders can be placed according to usual local process. The vendors have been notified to provide Medbuy contracted pricing when these medications are ordered by CON Pharmacies. Medbuy is also developing a communication channel to inform CON pharmacies directly of changes regarding BCCA reimbursable drugs. Until this process is fully in place, information will be provided directly by the BC Cancer Agency via the Systemic Therapy Update Newsletter.

The first drugs requiring a change in vendor are:

- carboplatin
- doxorubicin
- vincristine

The previous vendor was Mayne; the new vendor is Novopharm.

If you have any questions, please contact:

Dianne Kapy (BCCA) 604-930-4052
Susan Walisser (BCCA) 250-519-5508
Nancy Barry (Medbuy) 604-542-9040
Dr. Susan O'Reilly (BCCA) 604-877-6000
Ron McKerrow (PHSA) 604-675-741

PROVINCIAL SYSTEMIC THERAPY PROGRAM POLICIES

Community Adherence to Chemotherapy Process Standards Many people with cancer throughout British Columbia receive chemotherapy treatment services in their home communities in health care facilities. The BC Cancer Agency recognizes the need for specialized knowledge and skill required by physicians, nurses and pharmacists in order to provide this care safely.

To support safe practice related to chemotherapy administration and care, the BC Cancer Agency has a number of resources available on its website (www.bccancer.bc.ca), including:

- policies and procedures (www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Policies)
- cancer management guidelines (www.bccancer.bc.ca/HPI/CancerManagementGuidelines)
- chemotherapy protocols (www.bccancer.bc.ca/HPI/ChemotherapyProtocols)
- patient education information (www.bccancer.bc.ca/HPI/DrugDatabase/DrugIndexPt)

We would like to draw your attention to the Provincial Systemic Therapy Program Policy III-10: Chemotherapy Process (see summary below). This policy outlines standards and procedures to be followed by physicians, nurses, and pharmacists to ensure the safe prescribing, preparation, and administration of chemotherapy agents. Please circulate this material to the professional groups involved in providing chemotherapy services to people with cancer.

Susan E. O'Reilly
Leader, Systemic Therapy Program

Fiona Bees
Interim Provincial Professional Practice Leader - Nursing

Susan Walisser
Chair, Provincial Pharmacy Professional Practice Council

Summary of Systemic Therapy Program Policy III-10: Chemotherapy Process

The BC Cancer Agency has a number of policies available on the website to provide standards for the treatment and care of people receiving chemotherapy. Policy III-10 (www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Policies) outlines the process steps to follow to ensure the safe prescribing, preparation, and administration of cytotoxic agents.

These steps describe the activities of the three professional groups involved in the treatment of patients receiving chemotherapy- physicians, pharmacists, and nurses.

The physician, pharmacist, and nurse each have specific contributions to this process, but *all* have responsibility to calculate body surface area, and the protocol- specific dosage, route, timing, and duration of each drug administered to the identified patient. All three professionals are responsible for reviewing the appropriate patient-specific laboratory values, allergies, alerts, and other protocol specific parameters.

This “three-way” checking process provides the necessary safety net to prevent errors in the treatment process.

Integral to the process of prescribing, preparing, and administering chemotherapy is regular, ongoing assessment and monitoring of the patient to determine the individual’s response to the treatment. Assessment, including focused physical examination and interview of the patient, is necessary to determine therapeutic benefit and address treatment toxicities and side effects during each cycle of chemotherapy.

Other important aspects of this policy include:

- A maximum of a 5% variance (according to protocol dosages) in dosage calculation is permitted.
- All physicians’ prescriptions for cytotoxic drugs must be *written*. Any changes to an order or prescription must be signed and dated by the physician *before* the treatment is dispensed or administered.
- Any discrepancies identified by the pharmacist and/or nurse during their checking processes will be discussed with the prescribing physician. Documentation of the discrepancy and the resolution will be documented in the patient record.
- Individualized patient information and education is provided by physicians, pharmacists, and nurses. This includes verbal and written information.

The chemotherapy process is an example of physicians, pharmacists, and nurses working collaboratively to ensure the safe treatment and care of patients receiving cytotoxic medications.

HIGHLIGHTS OF PROTOCOL CHANGES

A new treatment protocol for the treatment of metastatic colorectal cancer - UGICAPIRI - is now available. There are now 4 protocols available for the treatment for palliative combination therapy of metastatic colorectal cancer involving either irinotecan or oxaliplatin and/or capecitabine. All four of these protocols now have consistent dose modification sections designed and revised for clarity and updates to the Precautions section.

Several Lymphoma protocols have been recently been revised. These revisions include:

- potential shortening of dosing intervals of the CHOP regimens (LYCHOP, LYCHOPR) dependent on haematological parameters
- clarification of the timing of hydrocortisone in the LYCVPPABO regimen, and
- extended number of fludarabine treatment cycles in responders for the treatment of low-grade lymphoma and CLL (LYFLU).

NURSING UPDATE

Chemotherapy Nurse Certification Congratulations to the following RNs who have completed BCCA Chemotherapy Certification since May 2003.

Regional Cancer Centre Nurses

Rachelle Bigold, VC Tatjana Behringer, VC Carlene Meilleur, VIC Catherine Pankras, VC

Community Cancer Centre Nurses

Burnaby Natti Astronomo Kamloops Jacquie Ciancone
Dorothy Villaneuva Allison Fillipic
Gayle Wou
Campbell River Cindy Headrick Kelowna Tracy Drew
Comox Patricia Kendall Trail Barb Koschik

Community Cancer Service Nurses

Dawson Creek Natalie Manhard Prince Rupert Jennifer Nelson

Community Hospitals

Quesnel Shelly Papineau 100 Mile House Nicola Maughn
Nishi Minas
Grand Forks Ainsley Gullage Sechelt Judi Oldham

Articles of the Month

1. Duhamel, F., and Dupuis, F. (2004). Guaranteed Returns: Investing in Conversations with Families of patients with Cancer. *Clinical Journal of Oncology Nursing*. February 8(1), pp. 1-7.

This article provides a useful framework for communicating with cancer patients and their families. The authors describe specific strategies for investing in meaningful conversations with those we care for. These strategies reflect the use of a model that attends to communication in four key areas: acknowledging the family's existence, the family's experience, its expertise, and also acknowledging the need to maintain hope.

2. Schmidt, K., and Wood, B. (2003). Trends in cancer therapy: role of monoclonal antibodies. *Seminars in Oncology Nursing*, 19(3), pp. 169 – 179.

For all those whose interest was piqued by presentations at the recent 1st Annual Systemic Therapy Nurses' Clinical Update, this article briefly reviews immunology, the function of monoclonal antibodies (Moabs), the classification of Moabs, and outlines current approaches to use of specific monoclonals in clinical practice. The entire August 2003 edition of *Seminars in Oncology Nursing* was devoted to discussion of "future therapies" and was mentioned by Lorraine Montoya in her presentation on gene therapy.

BENEFIT DRUG LIST

The current Benefit Drug List, Class II forms and Undesignated Indication Application forms are available on the BC Cancer Agency website (<http://www.bccancer.bc.ca/ChemoProtocols/Forms/>) under Health Professionals Info, Chemotherapy Protocols, Frequently Used Forms.

LIST OF NEW AND REVISED PROTOCOLS

The **INDEX to BC Cancer Agency Protocol Summaries** is revised monthly (includes tumour group, protocol code, indication, drugs, last revision date and version). Protocol codes for treatments requiring “Undesignated Indication” approval are prefixed with the letter **U**.

- **(U)BRLAACD** revised (inflammatory breast cancer added to eligibility): Treatment of locally advanced breast cancer using doxorubicin and cyclophosphamide followed by docetaxel (Taxotere®)
- **(U)GICAPIRI** new: Palliative combination chemotherapy for metastatic colorectal cancer using irinotecan and capecitabine in patients unsuitable for GIFOLFIRI
- **(U)GICAPOX** revised (dose modifications reformatted): Palliative combination chemotherapy for metastatic colorectal cancer using oxaliplatin, and capecitabine
- **GIFOLFIRI** revised (dose modifications reformatted): Palliative combination chemotherapy for metastatic colorectal cancer using irinotecan, fluorouracil and folinic acid (leucovorin)
- **(U)GIFOLFOX** revised (dose modifications reformatted): Palliative combination chemotherapy for metastatic colorectal cancer using oxaliplatin, 5-fluorouracil and folinic acid (leucovorin)
- **HNDE** revised (reformatted, administration sequence of cisplatin and etoposide clarified): Therapy for recurrent and metastatic nasopharyngeal cancer using cisplatin and etoposide
- **LYCHOP** revised (dosing interval clarified): Treatment of lymphoma with doxorubicin, cyclophosphamide, vincristine and prednisone
- **LYCHOPR** revised (dosing interval clarified): Treatment of lymphoma with doxorubicin, cyclophosphamide, vincristine, prednisone and rituximab
- **LYCVPPABO** revised (hydrocortisone administration guideline clarified): Treatment of Hodgkin's disease with cyclophosphamide, vinblastine, procarbazine and prednisone
- **LYFLU** revised (treatment duration extended): Treatment of low-grade lymphoma or chronic lymphocytic leukemia with fludarabine

Protocols are available on the BC Cancer Agency website (<http://www.bccancer.bc.ca/ChemoProtocols/>) under Health Professionals Info, Chemotherapy Protocols.

CANCER MANAGEMENT GUIDELINES

The Cancer Management Guidelines are available on the BC Cancer Agency website (<http://www.bccancer.bc.ca/CaMgmtGuidelines/>) under Health Professionals Info, Cancer Management Guidelines.

PRE-PRINTED ORDER UPDATE

Pre-printed orders should always be checked with the most current BC Cancer Agency protocol summaries. The BC Cancer Agency Vancouver Centre has prepared chemotherapy pre-printed orders, which can be used as a guide for reference. An index to the orders can be obtained by Fax-back.

- **BRAJCAFPO** new: Adjuvant therapy for breast cancer using oral cyclophosphamide, doxorubicin and fluorouracil
- **UGICAPOX** new: Palliative combination chemotherapy for metastatic colorectal cancer using oxaliplatin, and capecitabine
- **LYCVPPABO** new: Treatment of Hodgkin's disease with cyclophosphamide, vinblastine, procarbazine and prednisone
- **LYPALL** new: Lymphoma palliative chemotherapy
- **(U)MYBORTEZ** new: Treatment of multiple myeloma with bortezomib

PATIENT EDUCATION

BRAJCAF Patient Handout has been renamed as **UBRAJCAF** to be consistent with the change in protocol code. This protocol has been replaced by other CAF-based adjuvant protocols (BRAJCAF-G, BRAJCAFPO).

Patient information handouts for cancer drugs are available on the BC Cancer Agency website (www.bccancer.bc.ca/DrugDatabasePt/) under Health Professionals Info, Cancer Drug Manual, Drug Information for the Patient. For treatment protocol specific information, go to the BC Cancer Agency website (www.bccancer.bc.ca) under [Health Professionals Info, Chemotherapy Protocols, Information for the Patient](#).

DRUG UPDATE

Lamivudine – PharmaCare Coverage In lymphoma patients with a history of hepatitis B infection, the chemotherapy required to attempt to cure the lymphoma can cause the hepatitis infection to flare back up. This occurs in about 40% of patients given chemotherapy for lymphoma. Patients found to have positive testing for either hepatitis B surface antigen (HBsAg) or antibody to hepatitis B core antigen (HBcAb) should be considered to be at risk for fulminant hepatitis, if treated with immunosuppressive chemotherapy, especially agents such as corticosteroids or purine analogues.

The BCCA Lymphoma Tumour Group recommends that all lymphoma patients should be tested for both HBsAg and HBcAb. If either test is positive, corticosteroids should be omitted from treatment and such patients should be treated with lamivudine 100 mg/day orally, for the entire duration of the chemotherapy (typically 3-6 months) and for two months afterwards. Such patients should also be monitored with frequent liver function tests and hepatitis B virus DNA at least every two months. If the hepatitis B virus DNA level rises during this monitoring, management should be reviewed with a hepatologist and consideration given to halting chemotherapy. Treatment with lamivudine can decrease the risk of a flare-up in the hepatitis to less than 10%.

Presently, BC Pharmacare is honoring individual requests for lamivudine for patients who are HBsAg positive or HBcAb positive during immunosuppressive chemotherapy. This means that after patients have paid their deductible, BC Pharmacare will cover any additional cost. This will be of particular use to patients of lesser means and with third party coverage.

To request lamivudine coverage, use the Limited Coverage Drug Special Access form "Lamivudine for hepatitis B" (www.healthservices.gov.bc.ca/exforms/pharmacare/5342fil.pdf). Although lamivudine is NOT covered for this indication according to this form, Pharmacare approval is usually forthcoming when the application is accompanied with a note indicating that the use of lamivudine is recommended following the BCCA Lymphoma Tumour Group guidelines (www.bccancer.bc.ca/HPI/CancerManagementGuidelines/Lymphoma/HD/3.4.15.htm).

FOCUS ON THALIDOMIDE FOR THE TREATMENT OF MULTIPLE MYELOMA

Standard melphalan-based therapy of multiple myeloma (MM) is unfortunately not curative, and many patients suffer a relapse. Secondary therapy with prednisone or dexamethasone alone offers the possibility of further responses, but treatment options are otherwise limited for patients with relapsed or refractory disease.

In the 1950's thalidomide, a derivative of glutamic acid, was used widely outside the US as a sedative/hypnotic and anti-inflammatory agent. It was withdrawn from world markets in 1961 because of its severe and widely publicized teratogenic effects. In 1998, the US Food and Drug Administration (FDA) approved the use of thalidomide, under a special restricted distribution program, for the treatment of erythema nodosum leprosum (ENL), a condition which had responded to thalidomide when it had been used as a sedative-hypnotic in patients with ENL.¹¹ Subsequent investigations uncovered multiple biologic effects of thalidomide, leading to its investigation in oncology.

While its exact anti-tumour mechanism is not fully known, thalidomide is known to affect the activity of various cytokines and to inhibit angiogenesis.^{1,2} The latter ability may be responsible for its activity against MM, a disease in which there is a high degree of bone marrow vascularization.

Singhal et al.² in 1999 evaluated single-agent thalidomide in a Phase II study of 84 patients with advanced and refractory MM. In 2001, Barlogie et al.³ continued the work of Singhal with an additional 85 patients. Doses began at 200 mg/day and escalated to 800 mg/day if tolerated. Complete or near-complete responses (measured by percent reduction in serum or urine paraprotein levels) were reported in 11% of patients. Overall survival at four years was 25%, and event-free survival at four years was 9%. Response rates in other studies have varied between 20% and 70%.⁴ Use of thalidomide in newly diagnosed MM patients produced at least a 50% reduction in paraprotein levels and a median response of approximately one year.⁴

Thalidomide, having minimal myelosuppressive properties, has been tested in combination with corticosteroids and/or cytotoxic chemotherapy. Dexamethasone has been shown to be active in up to 31% of patients who were unresponsive to or who had relapsed on thalidomide alone. Thalidomide in combination with agents such as cisplatin, cyclophosphamide, doxorubicin, etoposide and/or vincristine has produced complete or near-complete remissions in up to 24% of patients in small phase II studies.^{4,5}

Use of single-agent thalidomide is supported at BCCA (protocol [LYTHALID](#)) for MM unresponsive to standard melphalan, prednisone, pamidronate and dexamethasone therapy. Thalidomide is not commercially available in Canada. Information on obtaining it through Health Canada's Special Access Program and BCCA Class II drug registration is available at the BC Cancer Agency website (<http://www.bccancer.bc.ca/ChemoProtocols/Forms/>) under Health Professionals Info, Chemotherapy Protocols, Frequently Used Forms.

Thalidomide is provided as capsules for oral administration. The recommended starting dose for MM is 200 mg daily for 14 days, increasing every 14 days by 200 mg daily, to maximum acceptable toxicity or disease progression. Daily dose should not exceed 800 mg. Most patients are able to tolerate doses of 200-300 mg, but higher doses are usually not tolerated for very long. Thalidomide does not appear to be hepatically or renally metabolized; therefore, no dosing adjustments are required in hepatic or renal dysfunction.⁵

Thalidomide is highly teratogenic, capable of causing severe birth defects or fetal death, even after a single dose. Celgene Corporation, the manufacturer of thalidomide, states that females of childbearing potential must use two methods of contraception, beginning four weeks prior to the start of thalidomide use, during thalidomide use, and for four weeks after the last dose. Celgene also states that males, while taking thalidomide and for four weeks after the last dose, must use condoms.⁵

Most side effects reported^{2,4,5} in MM patients taking thalidomide 200 – 800 mg/day as a single agent were mild or moderate (grade 1-2) and dose-related. Drowsiness, constipation, weakness, fatigue, tingling or numbness of hands and feet, dizziness and rash were most common, with more than 90% of patients experiencing some side effects at 800 mg/day. Thrombotic events have been reported when thalidomide is used in combination with chemotherapy and/or corticosteroids.⁶ Reversible acute renal failure has been reported in a patient receiving thalidomide.⁷ Increases in creatinine and hypocalcemia have been reported in individual cases when thalidomide is given concurrently with zoledronic acid.^{8,9} Caution should be used if other sedating medications or those associated with peripheral neuropathy are used concurrently with thalidomide.⁵

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CANCER DRUG MANUAL

The Cancer Drug Manual is available on the BC Cancer Agency website www.bccancer.bc.ca/cdm/.

Unconventional Cancer Therapies Manual is available on the BC Cancer Agency website www.bccancer.bc.ca under Patient/Public Info, Unconventional Therapies. The manual consists of 46 short monographs on the more commonly used unconventional cancer therapies (e.g., Essiac, vitamins, teas, shark cartilage) and includes tips for the patient and family on how unconventional therapies can be evaluated. For each therapy the manual provides proponent/advocate claims, as well as evidence-based evaluation/critique quotations from the literature.

This manual is currently being revised and the Fourth Edition will be published in the near future.

Departure of Dr. Robin O'Brien, Provincial Drug Information Specialist

With considerable sadness, but with best wishes for her future, the Provincial Systemic Therapy Program announces the recent retirement of Dr. Robin O'Brien at the end of January 2004. Robin has been an outstanding leader in the development and communication of oncology pharmacy knowledge to physicians, pharmacists, nurses and other health care providers, and patients across the province. She has been an invaluable resource to the Program and will be particularly missed by Dr. Susan O'Reilly who has counted on Robin's expertise for some of her toughest cases.

Over the years, Robin has served as pharmacy representative in various committees, including the Breast Tumour Group, Breast Systemic Policy Group and Breast Site Executive Committee with NCIC.

She taught Oncology Pharmacology and Therapeutics to undergraduate pharmacy students, and lectured extensively primarily on cancer drug therapy, natural health products and pharmacotherapy for dental teams.

She served as an expert reviewer for the Canadian Cancer Society and Natural Medicines Comprehensive Database and is until her retirement the editor of BC Cancer Agency's Unconventional Cancer Therapies Manual.

Robin has been involved as co-investigator in various research projects including a BCCA study researching the impact of pharmacist counseling on natural health products (ongoing) and the ABBA study - a student project in emergency medicine that morphed into a major study with almost 1000 participants (publication pending).

This year, the Canadian Society of Hospital Pharmacists presented Robin with the Pharmascience Award for Patient Care Enhancement (2003). In the past, Robin has received awards for Pharmacy Practice Commitment to Care Award for Technological Innovation (2002) and from the Canadian Society of Hospital Pharmacists Faulding Award for Oncology (2000/2001).

Although Dr. O'Brien has left her role at the Agency, she will continue to provide patient counseling services on conventional and unconventional therapies with the Pharmacotherapy Consulting Group (Tel: 604-224-3784, drobrien@pharmacotherapygroup.com, www.pharmacotherapygroup.com). We wish Robin well in her new adventure to continue to expand the scope of pharmacy practice.

Dr. Saira Mithani and Dr. Mário de Lemos will continue to provide provincial drug information service at the BC Cancer Agency (Tel: 604-877-6098 local 6275, email: druginfo@bccancer.bc.ca).

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