

Systemic Therapy Update

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for health professionals who care for cancer patients
Available on website www.bccancer.bc.ca

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

BENEFIT DRUG LIST

The following changes have been made to the Benefit Drug List by the Provincial Systemic Therapy Program effective 1 November 2002:

- Busulfan Injectable changed to Class I for pediatric patients who cannot swallow oral busulfan
- Cabergoline changed to Class I for second line suppressive therapy for prolactinomas (CNCAB)
- Docetaxel new class II indications for breast cancer (BRAVDOC7) and prostate cancer (GUPDOC)
- Fludarabine Oral Tablet added to Class I as an alternative to fludarabine injectable (LYFLU)
- **Gemcitabine** new Class II indications added for gynecological cancers (GOOVGEM), lymphoma (LYGDP, LYPALL) and mesothelioma (LUPG); new indication (Undesignated Indication approval required for each patient) added for germ cell cancers using paclitaxel and gemcitabine (UGUTAXGEM)
- Interferon Class II indication added for melanoma (SMAJIFN)
- Irinotecan Class II indication revised for colorectal cancer (GIIRINALT)
- Paclitaxel (Undesignated Indication approval required for each patient) Palliative therapy for germ cell cancers using paclitaxel and gemcitabine (UGUTAXGEM)
- Temozolomide Class II indications revised for brain tumours (CNTEMOZ)
- Trastuzumab Class II indication added as single agent therapy for breast cancer (BRAVTR)

If applicable, a Class II form or Undesignated Indication application must be completed and submitted to the Provincial Systemic Therapy Program before the drug will be dispensed at a regional cancer centre or reimbursed to a community hospital. The current Benefit Drug List, Class II forms and Undesignated Indication application forms are available on the BC Cancer Agency website (www.bccancer.bc.ca) under Health Professionals Info, Chemotherapy Protocols, Frequently Used Forms.

HIGHLIGHT OF PROTOCOL CHANGES

Breast Two new protocols have been introduced. The first, one, BRAVDOC7, is a new weekly docetaxel regimen introduced as an additional option for patients with poor tolerance to BRAVDOC or high doses of dexamethasone used for the protocol. Weekly docetaxel has been shown to be active and well tolerated by elderly and/or poor performance status patients with advanced breast cancer. The second protocol, BRAVTR, is the use of the HER-2 monoclonal antibody, trastuzumab, as a single agent palliative therapy in patients with HER-2 positive metastatic breast cancer.

Head and Neck UHNRAMI is a new treatment protocol that employs amifostine, a radioprotective agent, in the setting of radical/curative radiotherapy for head and neck cancers. Patients treated with high dose radiation for head and neck cancers often experience dose-limiting mucositis and xerostomia when substantial amount of salivary glands are included in the treatment fields. Xerostomia can result in substantial impact on patients' quality of life due to the associated difficulty with speaking and eating, increased risk for dental caries, loss of teeth, oral bone loss and infections. See **Drug Update** for more details on amifostine.

Lymphoma A number of changes in the treatment of lymphomas are introduced in this issue. First, the use of the LYICE (ifosfamide, carboplatin, etoposide) protocol for relapsed aggressive histology lymphoma is replaced by the LYGDP (gemcitabine, dexamethasone, cisplatin) regimen. Unlike the LYICE protocol which requires a 3-4 day hospitalization and routine filgrastim, the LYGDP is an entirely out-patient regimen and filgrastim is not usually needed. These two regimens appear to be equally effective based on the available phase II data. A completed Class II form is required for the use of gemcitabine for this indication.

Second, the high-dose LYECV (etoposide, cyclophosphamide, vincristine) regimen will no longer be recommended for patients with advanced stage mantle cell lymphoma. The current recommendation is to treat with 6 cycles of LYCHOP protocol instead. This decision is based on the fact that there is now sufficient information to show that these patients are not doing sufficiently

better than those treated with simple standard outpatient chemotherapy.

Third, oral fludarabine tablets are now available in Canada and has been added as an alternative to the intravenous fludarabine in the LYFLU regimen. Note that the dose of oral fludarabine is 40 mg/m² and the need for dose reduction or avoidance of this agent in the face of renal dysfunction still applies.

Fourth, gemcitabine is added as a palliative agent for the treatment of relapsed Hodgkin's lymphoma and peripheral T-cell lymphoma (LYPALL). Phase II studies have shown that gemcitabine is an active drug for many different types of lymphomas. Based on the literature and our own intra-provincial experience, the response rate to single agent gemcitabine for advanced relapsed Hodgkin's lymphoma, peripheral T-cell lymphoma and mycosis fungoides is in the 50 percent or higher range. A completed Class II form is required for the use of gemcitabine for this indication.

Finally, the use of intrathecal chemoprophylaxis (LYIT) has been revised for patients with bone marrow positive diffuse large cell lymphoma who have reached a complete remission. Based on recent publications and our own internal BC data, intrathecal therapy is no longer recommended for patients with bone marrow positive diffuse large cell lymphoma of B- or T-cell type, advanced stage testicular diffuse large B-cell lymphoma and epidural diffuse large B-cell lymphoma. However, chemoprophylaxis should continue to be given to patients with paranasal sinus lymphoma.

Neuro-Oncology The indications of temozolomide (CNTEMOZ) has been revised to include first line therapy for low grade oligodendrogliomas (12 cycles), as well as a first line alternative to lomustine (CNCCNU) and the PCV (procarbazine, lomustine, vincristine) regimen (CNMODPCV) for recurrent malignant gliomas and anaplastic oligodendrogliomas.

Sarcoma The use of an adjuvant doxorubicin therapy regimen (SAAJA) is now recommended for all healthy patients with high grade (Gr 2 or 3), large (5 cm or greater) soft tissue sarcomas (STS) involving the extremities. This recommendation is based on the findings of the Sarcoma Meta-Analysis Collaboration (SMAC) of the Cochrane Collaborative. The SMAC report combined the results of 14 randomized trials that treated STS patients comparing doxorubicin-based regimens

with no treatment. There was significant benefit for all STS patients in terms of local relapse free rate, distant recurrence free rate, relapse free survival rate and a trend for improved overall survival, as well as a significant 7% improvement in overall survival for the subset of extremity STS patients. The eligibility of adjuvant doxorubicin therapy would <u>not</u> be limited by age, though premorbid health status and perceived ability to tolerate full doses of this treatment should be taken into account before making a definite recommendation.

LIST OF NEW AND REVISED PROTOCOLS

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

- BRAVCAD revised (docetaxel dilution volume and infusion rate): Palliative therapy for metastatic breast cancer using docetaxel and capecitabine
- BRAVDOC revised (docetaxel dilution volume and infusion rate): Palliative therapy for metastatic breast cancer using Docetaxel (Taxotere®)
- BRAVDOC7 new: Palliative therapy for metastatic breast cancer using weekly docetaxel (Taxotere®)
- **BRAVEXE** revised (eligibility): Palliative Therapy for advanced breast cancer using exemestane (Aromasin®)
- BRAVTR revised (requirement for undesignated indication approval removed):
 Palliative therapy for metastatic breast cancer using trastuzumab (Herceptin®)
- CNCAB revised (class form requirement removed): Second line suppressive therapy for prolactinomas using cabergoline
- **CNMODPCV** revised (number of treatment cycles, maximum vincristine dose, vincristine dilution): Modified PCV chemotherapy of brain tumours using procarbazine, lomustine (CCNU) and vincristine
- CNTEMOZ revised (title, eligibility, antiemetics and treatment cycles): First line therapy for malignant brain tumours using temozolomide
- GIIRINALT revised (requirement for undesignated indication approval removed):
 Second-line treatment for 5-FU refractory

- metastatic colorectal cancer using weekly scheduled irinotecan
- GOOVCATR revised (dose modifications)
 Second line treatment using paclitaxel and carboplatin for epithelial ovarian cancer relapsing after primary treatment
- **GOOVGEM** new: Palliative chemotherapy for re-treatment of ovarian, tubal, and peritoneal cancer using gemcitabine
- GUBVAL new: Palliative therapy for BCGrefractory bladder Tis in patients unfit for cystectomy using intravesical valrubicin
- GUPDOC new: Palliative therapy for metastatic hormone refractory prostate cancer using docetaxel
- UGUTAXGEM new (Undesignated Indication approval required for each patient): Palliative therapy for germ cell cancers using paclitaxel and gemcitabine
- UHNRAMI new: Radioprotection in head and neck radiation using amifostine
- **ULUCISDOC** revised (docetaxel dilution volume and infusion rate): First-line treatment for advanced non-small cell lung cancer with docetaxel (Taxotere®) and cisplatin
- **LUDOC** revised (docetaxel dilution volume and infusion rate): Second-line treatment for advanced non-small cell lung cancer (NSCLC) with docetaxel (Taxotere®)
- LUPG revised (requirement for undesignated indication approval removed): Treatment of malignant mesothelioma with cisplatin and gemcitabine
- LYCHOP revised (eligibility for intrathecal chemotherapy): Treatment of lymphoma with doxorubicin, cyclophosphamide, vincristine and prednisone
- LYECV revised (indication for Mantle cell lymphoma deleted): Consolidation for lymphoma using etoposide and cyclophosphamide and vincristine
- **LYFLU** revised (oral fludarabine added): Treatment of low grade lymphoma or chronic lymphocytic leukemia with fludarabine
- **LYGDP** new (replacing LYICE): Treatment of lymphoma with gemcitabine, dexamethasone and cisplatin
- LYICE deleted (replaced by LYGDP):
 Treatment of lymphoma with ifosfamide, carboplatin and etoposide

- LYIT revised (eligibility, tests, treatment):
 Treatment of lymphoma using intrathecal methotrexate and cytarabine
- LYPALL revised (gemcitabine added):
 Lymphoma palliative chemotherapy
- SAAJA new: Doxorubicin for adjuvant use for patients with non-metastatic operable large high grade soft tissue sarcoma
- **SMAJIFN** revised (requirement for undesignated indication approval removed): Adjuvant therapy of high risk malignant melanoma with high dose interferon (HDIFN) ∞-2b

Protocols are available on the BC Cancer Agency website (www.bccancer.bc.ca) under Health Professionals Info, Chemotherapy Protocols.

CANCER MANAGEMENT MANUAL

The Cancer Management Manual is available are available on the BC Cancer Agency website (www.bccancer.bc.ca) 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.

- BRAJCEF revised (reformatted): Adjuvant therapy for breast cancer using cyclophosphamide, epirubicin and fluorouracil
- **BRAJCEF-G** new: Adjuvant therapy for breast cancer using cyclophosphamide, epirubicin, fluorouracil and filgrastim (G-CSF)
- BRAVNAV revised (tests, premedications, precautions): Palliative therapy for metastatic breast cancer using vinorelbine (Navelbine®)
- BRAVTRNAV revised (bookings for 3-weekly doctor's appointments): Palliative therapy for metastatic breast cancer using trastuzumab (Herceptin®) and vinorelbine
- BRAVTRAP revised (eligibility to be consistent with protocol): Palliative therapy for metastatic breast cancer using trastuzumab (Herceptin®) and paclitaxel (Taxol®) as first-line treatment for recurrent breast cancer refractory to anthracycline adjuvant chemotherapy

- BRINFCEF revised (reformatted): Therapy for inflammatory breast cancer using cyclophosphamide, epirubicin and fluorouracil
- **BRINFCEF-G** new: Therapy for inflammatory breast cancer using cyclophosphamide, epirubicin, fluorouracil and filgrastim (G-CSF)
- BRLACEF revised (reformatted): Therapy for locally advanced breast cancer using cyclophosphamide, epirubicin and fluorouracil.
- BRLACEF-G new: Therapy for locally advanced breast cancer using cyclophosphamide, epirubicin, fluorouracil and filgrastim (G-CSF)
- UGIFOLFOX new: Palliative combination chemotherapy for metastatic colorectal cancer using oxaliplatin, 5-fluorouracil and folinic acid (leucovorin)
- LYCHOP-R revised (booking time): Treatment of lymphoma with doxorubicin, cyclophosphamide, vincristine, prednisone and rituximab

PATIENT EDUCATION UPDATE

Amifostine Patient Information Handout is now available. Amifostine is used as radioprotective agent for patients receiving high dose radiation. See Drug Update for more information.

Fludarabine (Oral) Patient Information Handout is now available.

Goserelin and Leuprolide Patient Information Handouts have been corrected for typographical error.

Valrubicin Patient Information Handout is now available.

Patient information handouts for cancer drugs are available on the BC Cancer Agency website (www.bccancer.bc.ca) under Health Professionals Info, Drug Database.

DRUG UPDATE

Amifostine is a sulfhydryl prodrug used as a radioprotective and cytoprotective agent. Its active metabolite is readily taken up by cells where it acts by scavenging the free radicals generated in tissues exposed to radiation and chemotherapy, as well as reactive metabolites of cisplatin and alkylating agents. Healthy cells are protected preferentially

due to increased uptake of amifostine and more rapid metabolism to the active sulfhydryl metabolite because of greater phosphatase activity and higher pH, as compared to tumour cells. Amifostine and metabolites have been shown to be present in 100 times the concentration in healthy cells compared to tumour cells.

Changes in Special Access Programme Health Canada has recently changed its requirements for accepting requests for Special Access Programme (SAP) medications such as amifostine, bexarotene, oxaliplatin and thalidomide. The major change is to require the use of the Health Canada form when requesting a SAP medication and to require the physician's consent to the following statements:

- I am aware that by accessing this drug through the SAP, the sale of the drug is exempt from all aspects of the *Food and Drugs Regulations* including those respecting the safety, efficacy and quality.
- I agree to provide a report on the results of the use of the drug including information on Adverse Drug Reactions in accordance with the current regulations and, on request, to account for quantities of the drug received.

The link to the Health Canada SAP form can be found on the BC Cancer Agency website (www.bccancer.bc.ca) under Health Professionals Info, Chemotherapy Protocols, Frequently Used Forms, or directly from Health Canada website.

CANCER DRUG MANUAL

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

COMMUNITIES ONCOLOGY NETWORK

Access **BCCA** Increasing to Resources A common request from nurses around the province is for greater access to information about BCCA nursing procedures. agency policies related to safe while the administration and handling of chemotherapy drugs are already included in the website, other frequently-used documents are not yet available. Examples of other, frequently used (and requested) nursing references include current procedures for Central venous catheter care, including PICC, IVAD and Hickman lines care.

We are committed to making current references and resources readily available to all BCCA nurses. In the next few months you will note a progressive move to include more nursing information on the BCCA website. Stand by for updates on this area!

Submitted by Judy Oliver Education Resource Nurse

Survey Results for Pharmacy Professional Development In July 2002, the Pharmacy CON Educators distributed a professional development needs assessment survey to 80 CON pharmacists throughout British Columbia. The survey is now complete and the results have been processed. Thank you to all of you who contributed to the survey and resubmitted the information a second time when a technical error erased the original data. Eighty surveys were distributed and fifty-one responses were received. This represented a return rate of 64%.

The purpose of Section One was to develop a profile of the CON pharmacist. We learned that the majority of the respondents were involved in some aspect of their hospital's oncology practice: preparation of cytotoxics, training of staff, dispensing, clinical, counselling patients and billings. For 51% of the respondents, oncologyrelated activities represented less than 25% of their hospital practice. Eighty percent said that oncology represented less that 50% of their hospital practice. This section also identified that technicians play an integral part of CON practice. Eighty-six percent of the respondents stated that technicians are involved in the preparation of parenteral cytotoxic drugs at their hospital. Sixty-four percent of the technicians were trained by other technicians rather than by pharmacists.

In Section Two, the CON pharmacists were asked where their priorities lie with respect to their pharmacy oncology practice. The top four priorities in this area were identified to be:

- Interpretation and Clinical application of protocols
- Guidelines for safe handling of cytotoxic medications
- General management of chemotherapy side effects
- General concepts in oncology

We also identified key issues confronting the CON pharmacists: staffing shortages, training needs and budget constraints.

Section Three of the survey dealt with how best to deliver an oncology education program. The top four methods were:

- Regional sessions at the nearest BCCA Centre
- Practicums at Cancer Centres
- Web-based
- Text-based

Approximately 50% of the respondents have attended a BCCA Annual Cancer Conference in November. Those that have not attended cited reasons such as staffing, budget, travel or the fact that oncology was not a high priority in their hospital practice.

The challenge now facing the CON Educators is to design an oncology education program that will fit the needs of as many of our CON partners as possible. Our first step is to create an initially text-based educational module on "Interpretation and Clinical Application of Protocols." A text-based program is chosen because it is the most practical and far-reaching, although it was not the first choice overall. Our plan is to pilot the first module early next year. Conversion to a web-based program, practicums and regional sessions will be developed at a future date.

Our thanks to those who helped us achieve this goal. As a show of our appreciation, we held a random draw from those who submitted their name after completion of the survey. The winners of a \$75.00 book prize gift certificate were:

- Karen Dusangh (Richmond General Hospital)
- Karen George (West Coast General Hospital)
- Terry Malo (Penticton Regional hospital)
- Ian Petterson (Shuswap Lake Hospital)

For more information on the development of the provincial pharmacy oncology-education program, please contact your regional Pharmacy CON Educator.

Submitted by Dawn Annable Pharmacy CON Educator-Fraser Valley

Changes in Contact Phone Number Please note that the following extensions have been changed:

1. **CON billings:** 6277 (previously 2515)

2. **Undesignated Indication Approval**: 6277 (previously 2515)

These extensions can be reached through (604) 877-6098 or toll free 1-800-663-3333.

PROVINCIAL SYSTEMIC THERAPY PROGRAM POLICIES

Policy on Administration of Intrathecal Chemotherapy The Policy on the Administration of Cytotoxic Drugs by the Intrathecal Route via Lumbar Puncture or Ommaya Reservoir (Policy III-50) has been revised to delete the cross-reference to the vinca alkaloids labelling policy.

BC Cancer Agency Systemic Therapy Policies are available on the BC Cancer Agency website (www.bccancer.bc.ca) under Health Professionals Info, Chemotherapy Protocols, Policies and Procedures.

LIBRARY/CANCER INFORMATION CENTRE

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.

CONTINUING EDUCATION

Presentation on Symptom Management Karima Velji, an advanced practice nurse with an extensive background in cancer nursing practice, education, and research, will present "Implementing Research in Practice: Symptom Management" on Wednesday evening, 27 November, 2002. Please join us at one of the four regional cancer centres for a light dinner at 6 pm, followed by the video-linked presentation at 7 pm.

For more details, please call: Vancouver Island Centre - Jodi Graham (250) 519-5573; Centre for the Southern Interior - Dixie Rosher (250) 712-3975; Vancouver and Fraser Valley Centres - Isabel Lundie (604) 877-6098, local 2623.

BCCA Annual Cancer Conference The BC Cancer Agency will hold its Annual Cancer Conference 2002 at the *Renaissance Harbourside Hotel* in Vancouver.

The 3-day agenda includes the Canadian Strategy for Cancer Control, Medical Scientific Conference and Provincial Oncology Professionals meeting.

The Partners in Care Conference on Thursday, November 28th will be devoted to *Implementing the Canadian Strategy for Cancer Control in BC and Yukon*, a workshop presented by the BC Cancer Agency (BCCA), Canadian Cancer Society (CCS) and Canadian Cancer Advocacy Network (CCAN). This workshop is by invitation only.

The *Medical/Scientific Conference* on Friday November 29 all day and Saturday November 30 until noon is devoted to *Immune System and Cancer*.

The *Provincial Oncology Professionals* will hold their discipline-specific education and business meetings on either Friday November 29 or Saturday November 30.

For more details, please call (604) 877-6098 local 2744. Please don't forget to check out our website for further details!

(www.bccancer.bc.ca/HPI/AnnualCancerConf/defa ult.htm)

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Fraser Valley Centre (FVCC)	(604)-930-2098	Toll-Free 1-(800)-523-2885
Vancouver Centre (VCC)	(604)-877-6000	Toll-Free 1-(800)-663-3333
Vancouver Island Centre (VICC)	(250) 519-5500	Toll-Free 1-(800)-670-3322

REGIONAL CANCER CENTRE ACCESS

BULLETIN UPDATES		LOCATION				
Cancer Drug Manual		H:\everyone\systemic\chemo\cancer drug manual monographs				
Pre-Printed Orders		H:\everyone\systemic\chemo\Orders\VCC				
Index of Pre-Printed Orders		<u>Index.doc</u>				
BRAJCEF	BRAVNAV	BRAVTRAP	BRINFCEF-G	BRLACEF-G	LYCHOP-R	
BRAJCEF-G	BRAVTRNAV	BRINFCEF	BRLACEF	UGIFOLFOX		
Protocol Summaries		H:\everyone\systemic\chemo\Protocol\"tumour site"			te"	
Index of Protocol Summaries		<u>Index_NT</u> or <u>Index_W6</u>				
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For easy access, double-click your systemic chemo icon. We appreciate your comments. Write us at bulletin@bccancer.bc.ca

BC CANCER AGENCY SYSTEMIC THERAPY UPDATE FAX REQUEST FORM

FAX (604) 877-0585 bulletin@bccancer.bc.ca

TO SUBSCRIBE: FAX OR EMAIL YOUR REQUEST OR CALL @ 877-6098 LOCAL 2247

FOR URGENT REQUESTS PLEASE CALL (604) 877-6098 LOCAL 2247 OR TOLL-FREE IN BC 1-800-663-3333 LOCAL 2247 PLEASE FEEL FREE TO MAKE COPIES FOR YOUR COLLEAGUES

I WOULD PREFER TO RECEIVE THIS INFORMATION VIA:

☐ E-mail (Word 6.0)		@						
☐ Fax	()		Attn:					
UPDATES Please ☑ Fax-Back information below:								
All items								
Cancer Drug Manual Mor								
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BRAVDOC7	CNTEMOZ		LUPG		ICE			
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