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

## ANNUAL INDEX

The 2002 annual index or previous issues of the Systemic Therapy Update is now available on the BCCA website ([www.bccancer.bc.ca](http://www.bccancer.bc.ca)) under Health Professionals, Chemotherapy Protocols, Update Newsletter.

## HIGHLIGHTS OF PROTOCOL CHANGES

Two new protocols are announced in this issue of the Update. Both protocols require “Undesignated Indication” approval. Since the drugs involved in these protocols are not commercially available, Health Canada Special Access Program approval is also required prior to use.

The **ULYALEM** protocol outlines the use of alemtuzumab in patients with the common

B-chronic lymphocytic leukemia and the rare but aggressive T-cell prolymphocytic leukemia. Alemtuzumab is indicated for patients who are ineligible for bone marrow transplantation and whose disease is refractory to or has relapsed from alkylators and purine analogues. Alemtuzumab is a humanized monoclonal antibody directed against the surface antigen CD52 on normal and malignant B and T-lymphocytes. It binds to the CD52 antigen and triggers an immune response causing lysis of leukemic and normal cells.

The **ULUPA** protocol outlines the use of pemetrexed and cisplatin in patients with malignant pleural mesothelioma (MPM). MPM is an uncommon but aggressive neoplasm of the lining of the lung for which there has been no approved or effective chemotherapy. Pemetrexed is a methotrexate-related novel antifolate that inhibits thymidylate synthase and other folate-dependent enzymes. When used in combination with cisplatin, pemetrexed has been shown to improve survival, tumour response, and symptom control in MPM.

## BENEFIT DRUG LIST

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](http://www.bccancer.bc.ca)) under Health Professionals Info, Chemotherapy Protocols, Frequently Used Forms.

## LIST OF NEW AND REVISED PROTOCOLS

**INDEX to BC Cancer Agency Protocol Summaries** revised monthly (include 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**.

- **GUAVPG** revised (gemcitabine dosing with carboplatin): Palliative therapy for urothelial carcinoma using cisplatin and gemcitabine
- **ULUPA** new: Treatment of malignant mesothelioma with cisplatin and pemetrexed (ALIMTA®)
- **ULYALEM** new: Treatment of fludarabine-refractory B-chronic lymphocytic leukemia (B-CLL) and T-prolymphocytic leukemia (T-PLL) with alemtuzumab
- **LYCCOP** revised (cyclophosphamide preparation instructions): Treatment of Hodgkin's lymphoma using cyclophosphamide, vincristine and prednisone
- **SAIME** revised (typos corrected): Etoposide, ifosfamide-mesna for patients with newly diagnosed Ewing's sarcoma/peripheral neuroectodermal tumor (PNET) or rhabdomyosarcoma or advanced soft tissue or bony sarcomas

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

#### **CANCER MANAGEMENT MANUAL**

The Cancer Management Manual is available on the BC Cancer Agency website ([www.bccancer.bc.ca](http://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.

- **CNCCV** revised (1000 mL deleted from post-hydration): Adjuvant lomustine, cisplatin and vincristine in adult high-risk medulloblastoma or other primitive neuroectodermal tumour
- **GIENDO1** revised (dispense in glass bottle" added to carmustine order): Palliative therapy of pancreatic endocrine tumors using carmustine and fluorouracil
- **GIPGEM** revised (bookings): Palliative therapy for pancreatic adenocarcinoma cancer using Gemcitabine
- **LUDOC** revised (use of non-PVC equipment added): Second-line treatment for advanced

non-small cell lung cancer (NSCLC) with docetaxel (Taxotere®)

#### **PATIENT EDUCATION**

**Alemtuzumab (Campath®) and Pemetrexed (ALIMTA®)** Patient information handouts have been developed for these two drugs. For more information, see the **Highlights of Protocol Changes**.

**Natural Health Products and Cancer Therapy** A joint recommendation and patient information handout has been developed by the BCCA Departments of Medical Oncology, Radiation Oncology, Surgical Oncology, Pharmacy, Nursing and Nutrition. This handout advises cancer patients that the BC Cancer Agency does not recommend using natural health products (for example, herbs and supplements) during chemotherapy, radiation therapy or surgery. The recommendation was prompted by a recently published retrospective case control study from the Vancouver Island Centre that examined the effect of taking megadose supplements during adjuvant therapy for breast cancer. Although the study was underpowered and the results need to be confirmed, there was a trend for earlier recurrence and shorter survival with supplement use. This was clinically significant with an absolute difference in disease-free and overall survival of about 10% at 10 years (Lesperance ML et al. Br Cancer Res Treat 2002;76:137-43). The handout is available on the BC Cancer Agency website ([www.bccancer.bc.ca](http://www.bccancer.bc.ca)) under Health Professionals Info, Cancer Management Guidelines, Supportive Care and is linked to the Unconventional Cancer Therapies Manual. The healthcare professional's version is under development.

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

([www.bccancer.bc.ca](http://www.bccancer.bc.ca)) under Health Professionals Info, Chemotherapy Protocols, Information for the Patient.

## CANCER DRUG MANUAL

The Cancer Drug Manual is available on the BC Cancer Agency website [www.bccancer.bc.ca/cdm/](http://www.bccancer.bc.ca/cdm/).

## DRUG UPDATE

**Leuprolide (Lupron®)** is a BCCA Class I benefit drug for some patients with prostate cancer. Lupron® is available as 7.5 mg (1-month slow release), 22.5 mg (3-month slow release) and 30 mg (4-month slow release) depot injections. Abbott Laboratories has recently announced changes to the product line. As existing supplies are depleted, new Lupron® product will include the **LuproLoc™ safety device**. Packages with the new safety device can be identified by a yellow sticker reading "*Attention: Safety Device. Only Activate Post Injection.*"

In Canada, healthcare providers experience an estimated 60,000-80,000 needlestick injuries each year. LuproLoc™ is a needlestick prevention device that locks away the needle when activated. To activate, all that is required is a simple pressure of the thumb. Once activated, the device cannot be removed. Please ensure that the device is not activated until after the injection is given.

An information card, with a picture of the device and instructions for use, is available from Abbott Laboratories.

## PROVINCIAL SYSTEMIC THERAPY PROGRAM POLICIES

### Systemic Therapy Policy III-80- A New Provincial Clinical Practice Tool: Algorithm for Needle Placement/Catheter Patency in Central Venous Catheter Devices

Before the administration of treatments via a central venous catheter (CVC), steps are taken to verify catheter patency and correct placement of the device. These steps include careful inspection of the CVC site, assessment of the patient's response during access and use, and aspiration of the line to obtain blood return (Brown et al, 2001)

Lack of blood return may signal partial or complete occlusion of the CVC. Partial occlusion exists when solutions infuse but no blood return can be obtained. The CVC is completely occluded when fluids cannot be infused and blood return is absent (BCCA, 2001). No studies have provided evidence-based data as to when it is safe to give medications through a device without blood return (Camp-Sorrell, 1996, 2003).

Policy III-30 provides clinical direction for steps to take to ensure safe use of central venous catheters such as ports, PICC's, and **HICKMAN®** lines.

The policy can be found at: (ST policy address) and on the BCCA Nursing website (Nursing website address)

### References:

- BC Cancer Agency.(2001). Care of an occluded central venous catheter (C-80, C-86, I-40) in Nursing Practice Reference Manual. Vancouver, BC: BC Cancer Agency.
- Brown, K. et al (eds.) (2001). Chemotherapy and biotherapy: guidelines and recommendations for practice. Pittsburgh, PA: Oncology Nursing Society.
- Camp-Sorrell, D. (1996). Access device guidelines: Recommendations for nursing practice and education. Pittsburgh, PA: Oncology Nursing Society.
- Camp-Sorrell, D. (2003). Assessing venous access devices: when to obtain a venogram. Clinical Journal of Oncology Nursing, 7, 234-235.

### Other recommended reading:

- Mayo, D. and Peterson, D. (1995). Chemotherapy extravasation: a consequence of fibrin sheath formation around venous access devices. Oncology Nursing Forum, 22, 675-680.
- Nace, C. and Ingle, R.(1993). Central venous catheter "pinch-off" and fracture: a review of two under-recognized complications. Oncology Nursing Forum, 20, 1227-1236.
- Schulmeister, L. and Camp-Sorrell, D. (2000). Chemotherapy extravasation from implanted ports. Oncology Nursing Forum 27, 531-538.

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

## NURSING UPDATE

**Chemotherapy Nurse Certification**, Congratulations to the following nurses who have completed BCCA Chemotherapy Certification since February 2003.

### Community Cancer Centres

Lisa Chao (Richmond)  
Diana Ferguson (Trail)  
Debbie O'Brien (Cranbrook)  
Shona Panek (Powell River)

### Regional Cancer Centres

Kim Rushing (VC)  
Ana Fistic (VC)

**BCCA Nursing Website is growing!** The website is evolving! To get there from the home page, go to Cancer Management Guidelines, then scroll down to the Nursing link. Quicker still just click here on <http://www.bccancer.bc.ca/HPI/Nursing/default.htm> and save it as one of your favourites.

The 3 main sections (Education, References and Communication) are expanding.

The listing of nursing education events will be updated as new sessions are scheduled. Those nursing references that are closely related to oncology (i.e., chemotherapy, central venous catheters) are now mounted on the site. The reference section will also link you to Supportive Care references, such as Management of Radiation Skin Reaction, and Pain Management.

You can make a direct link to the ST Update through the Communication sections, and also read of activities and progress in "Nursing Notes", a quarterly publication from BCCA Nursing.

**A Useful Nursing Website** Cancersource.com is a wonderful, free educational link you will want to explore. It is produced in partnership with Oncology Nursing Society in the US. Cancersource posts a weekly newsletter for oncology nurses that contains a wide variety of topics related to patient care and support. As an example, the April 10 edition has a continuing education session called *Prostate Cancer: Hormone therapy*. You can also search back for previous continuing education sessions on specific cancers, treatments and symptom management. For example, the April 3 session was on Hypersensitivity in Cancer. The March 27 session was on Management of Pain in Cancer.

You can receive these weekly on-line bulletins automatically by going to [www.cancersourceRN.com](http://www.cancersourceRN.com) and clicking on *registration* to sign up.

### **FOCUS ON GEFITINIB (IRESSA®)**

**Gefitinib (Iressa® , ZD1839)** is a novel oral agent specific for epidermal growth factor receptor (EGFR) which is found on numerous tumors, such as those of the lung (non-small-cell lung cancer [NSCLC]), prostate, breast, pancreatic, bladder, head and neck. Increased EGFR activity has been shown to correlate with increased tumor growth, during the late stages of metastatic diseases where tumors are resistant to chemotherapy and prognosis is poor. Gefitinib blocks EGFR at the intracellular level by inhibiting signal transduction as it blocks the tyrosine kinase associated with EGFR. (1) Gefitinib is manufactured by AstraZeneca under the brand name Iressa®.

#### **What is its indication?**

Gefitinib 250 mg PO daily is currently licensed in Japan and being reviewed by the US Food and Drug Administration as second or third line treatment of NSCLC that is resistant to platinum based chemotherapy. The current option for patients with advanced or metastatic NSCLC who have failed platinum based chemotherapy is additional chemotherapy, usually with docetaxel (BCCA Protocol LUDOC), which has a limited response rate between 5.5-6.7%. (3)

Two phase II trials have reported clinically significant antitumor effect in advanced and metastatic NSCLC patients who previously received platinum based chemotherapy. (Table 1) Both studies did not have a comparative arm, and patients either received 250 mg or 500 mg a day of gefitinib. Both studies reported that 250 mg/day had as much antitumor activity as 500 mg/day, and that side effects such as diarrhea (65%), acne-like rash (55%) and asthenia (49%) were greater in the 500 mg/day treatment arm. (1,7,8)

	<i>Phase II Trial (8)</i>		<i>Phase II Trial (7)</i>	
	<i>250 mg/d</i>	<i>500 mg/d</i>	<i>250 mg/d</i>	<i>500 mg/d</i>
Response Rate (%)	11.8	8.8	18.4	19.0
Progression Free Survival (months)	2.0	2.0	2.7	2.8
Overall Survival (months)	6.2	6.1	7.6	8.1

Two major phase III trials have been presented as abstracts to illustrate the evidence for gefitinib use in non-small-cell lung cancer. The first trial combined gemcitabine and cisplatin with placebo, gefitinib 250 mg/day, or gefitinib 500 mg/day in 1903 patients. (4) The overall survival was 11.1, 9.9, and 9.9 months respectively. There was no

significant difference in time to progression-free survival (PFS) between the three arms of the study. No additional toxicities were reported for those patients in the chemotherapy plus gefitinib arms except dose-dependent diarrhea and skin rash. (4) The second trial combined paclitaxel and carboplatin with either placebo, gefitinib 250 mg/day, or gefitinib 500 mg/day in 1037 patients. The overall survival was 9.9, 9.8, and 8.7 months respectively. As with the first trial, there was no significant difference in time to PFS between the three arms of the study. Again, no additional toxicities were reported for those patient in the chemotherapy plus gefitinib arms except dose-dependent diarrhea and skin rash. (5)

### **Are there any drug interactions?**

Gefitinib does not induce the cytochrome P450 system (CYP). However, it is metabolised by CYP, specifically the CYP 3A4 enzyme. Concurrent administration of gefitinib with itraconazole, a potent CYP 3A4 inhibitor, resulted in a 80% increase in systemic exposure of gefitinib.(3) Hence, gefitinib may potentially interact with other known CYP 3A4 inhibitors (e.g., docetaxel, cannabinoids, etoposide, metronidazole, cimetidine, erythromycin) or be metabolised more quickly by inducers (e.g., dexamethasone).

### **What are the main side effects?**

Phase I/II trials report the main side effects to be diarrhea, nausea, asthenia, skin reactions (dry skin, acne, rash, pruritus), elevated ALT/AST. (1,3) These adverse drug effects ceased when the drug was discontinued. (1) Doses of 250 mg PO daily had fewer side effects than 500 mg PO daily. (3)

Recently, concerns have been raised regarding gefitinib and reports of interstitial lung disease (ILD) coming from Japan.(4) From July to December of 2002, there were 494 cases of ILD reported in Japan, with 124 of those cases resulting in the death of the patient. The incidence for the potential for ILD was estimated to be between 1-2 %. As a result, Japanese physicians must admit patients who are to receive gefitinib to hospital for four weeks after start of treatment. In response to these concerns, AstraZeneca released statements regarding internal data that stated 50 000 people worldwide have used gefitinib and the incidence has been less than 1%, which is lower than observed with other current lung cancer therapies. (2) ILD is a known complication of advanced lung cancer and

has been reported in clinical trials with both chemotherapy and radiotherapy for lung cancer. Two large Phase III trials, including 2100 patients, compared gefitinib to placebo for NSCLC. In these trials, there was no significant difference of ILD-type events between patients receiving gefitinib (1.1%), and those receiving placebo (0.9%). (5,6)

### **How is gefitinib obtained?**

Gefitinib requires undesignated approval prior to its use at the BCCA. Currently the drug is not approved for use in Canada, and prescribing physicians must obtain approval through the Special Access Programme (SAP) and from AstraZeneca.

Submitted by

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Reviewed by

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### **References**

1. Herbst, RS, Maddox, A, Rothenberg, ML, et al. Selective oral epidermal tyrosine kinase inhibitor ZD1839 is generally well -tolerated and has activity in non-small-cell lung cancer and other solid tumors: results of a phase I trial. *J Clin Oncol* 20;2002;p3815-3825.
2. Personal communication. Sonal Sodha, BScPharm, AstraZeneca, 28<sup>th</sup> January 2003.
3. FDA report, Briefing Document NDA 21-399.
4. Inoua, A, Yaijo, S, Maemondo, M, et al. Severe interstitial pneumonia and gefitinib. *Lancet* 2003;361:137-39.
5. Giaccone, G, Johnson DH, Manegold C, et al. A phase III clinical trial of ZD 1839 ('Iressa') in combination with gemcitabine and cisplatin in chemotherapy-naïve patients with advanced non-small-cell lung cancer (INTACT 1). *Ann Oncol* 2002;13 (Suppl 5):2, Abs 40
6. Johnson DH, Herbst R, Giaccone, G, et al. ZD 1839 ('Iressa') in combination with paclitaxel and carboplatin in chemotherapy-naïve patients with advanced non-small-cell lung cancer (NSCLC): Results from a phase III clinical trial (INTACT 2). *Ann Oncol* 2002;13 (Suppl 5):127-8, Abs 4680
7. Fukuoka M, Yano S, Giaccone G, et al: Final results from a phase II trial of ZD1839 ('Iressa') for patients with advanced non-small-cell lung cancer (IDEAL 1). *Proc Am Soc Clin Oncol* 21: 298a, 2002 (abstr 1188)
8. Kris MG, Natale RB, Herbst RS, et al: A phase II trial of ZD1839 ('Iressa') in advanced non-small-cell lung cancer (NSCLC) patients who had failed platinum- and docetaxel-based regimens (IDEAL 2). *Proc Am Soc Clin Oncol* 21: 292a, 2002 (abstr 1166)

### **LIBRARY/CANCER INFORMATION CENTRE**

**Unconventional Cancer Therapies Manual** is available on the BC Cancer Agency website [www.bccancer.bc.ca](http://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.

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<b>BULLETIN UPDATES</b>		<b>LOCATION</b>	
Cancer Drug Manual		H:\everyone\systemic\chemo\cancer drug manual monographs	
Pre-Printed Orders		H:\everyone\systemic\chemo\Orders\VCC	
CNCCV	GIENDO1	GIPGEM	LUDOC
Protocol Summaries		H:\everyone\systemic\chemo\Protocol\tumour site"	
Index of Protocol Summaries		Index_NT or Index_W6	
GUAVPG	ULYALEM	SAIME	
ULUPA	LYCCOP		
Patient Education Handout		H:\everyone\systemic\chemo\Pt Education	
Alemtuzumab		Pemetrexed	
Natural Health Products & Cancer Therapy			
Provincial Systemic Therapy Policies		H:\everyone\systemic\chemo\policies	
Reimbursement		H:\everyone\systemic\chemo\Reimburs	
Benefit Drug List (March 03)		BenefitList.doc	
Class 2 Form (March 03)		Class2.doc	

For easy access, double-click your systemic chemo icon.

We appreciate your comments. Write us at [bulletin@bccancer.bc.ca](mailto:bulletin@bccancer.bc.ca)

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