Systemic Therapy Update



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Website access at http://www.bccancer.bc.ca/HPI/ChemotherapyProtocols/stupdate.htm

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IN TOUCH phone list is provided if additional information is needed.

EDITOR'S CHOICE:

HIGHLIGHTS OF CHANGES IN PROTOCOLS, PRE-PRINTED ORDERS AND PATIENT HANDOUTS

The **Gastrointestinal Tumour Group** has introduced **cetuximab plus irinotecan** as a third line treatment for patients whose metastatic colorectal cancer is no longer responding to fluorouracil, irinotecan and oxaliplatin, and whose tumour has been shown to be of wild type KRAS (**UGIAVCETIR**). BCCA Compassionate Access Program (CAP) approval will need to be obtained prior to use. Note that cetuximab is given as 500 mg/m2 every two weeks without loading dose. This dosing schedule has been shown to be an active and safe option to the standard weekly regimen (Roca J et al. J Clin Oncol 2008;26: May 20 suppl; abstr 15122).

Patients being considered for cetuximab-irinotecan combination therapy or panitumumab monotherapy should be tested for KRAS. The requisition for KRAS testing is available online on the BCCA website under Laboratory Services → Pathology Request Forms (see <u>KRAS Test Request for Metastatic Colorectal Cancer</u>). Note that eligible patients should receive either cetuximab plus irinotecan regimen (**UGIAVCETIR**), or panitumumab monotherapy (**UGIAVPANI**), but not both.

For more details on KRAS testing, see **Panitumumab** in the **Drug Update** section in the June issue of the **Systemic Therapy Update**.

The Gastrointestinal Tumour Group has also introduced several other changes:

- 1. New patient information handouts (UGIRAJFFOX, UGIAJFFOX, UGIFOLFOX)
- 2. Bevacizumab infusion time shortened to 10 minutes (Reidy et al. J Clin Oncol 2007;25:2691-5)
- 3. Baseline tests clarified in bevacizumab-based protocols
- 4. Optional calcium and magnesium therapy added to adjuvant oxaliplatin-based protocols
- 5. Drug interaction between fluorouracil and phenytoin added to all fluorouracil-based protocols
- 6. Option of leucovorin dosing added to Dose Modifications (GIAVFL, UGIFFIRB, UGIFFOXB, GIFOLFIRI, UGIFOLFOX)
- 7. Timing of blood chemistry revised (GIAVFL, GIFOLFIRI, UGIFOLFOX)
- 8. Antiemetics clarified (UGIAJFFOX, UGICAPOX, UGIFOLFOX)

The **Genitourinary Tumour Group** has extended the total number of treatment cycles from 6 to 10 in the docetaxel protocol for hormone refractory prostate cancer (GUPDOC).

The **Head and Neck Tumour Group** has shortened the infusion time and hydration regimen for the high dose cisplatin concurrent with radiation for locally advanced nasopharyngeal cancer (HNLANPRT). A new patient information handout has also been introduced for this protocol.

The **Lung Tumour Group** has revised the eligibility criteria for erlotinib for non-small cell lung cancer (LUAVERL) and the pemetrexed-based protocols (LUAVPEM, LUMMPP).

The **Myeloma and Leukemia/BMT Tumour Groups** have revised the lenalidomide protocols (UMYLENDEX, ULKMDSL) regarding the monitoring of bloodwork during the first month of therapy.

DRUG UPDATE

Patient Assistance Program for Aprepitant (EMEND®) has now been closed to new patient enrolment as of July 2, 2009. Patients who have been enrolled prior to this notification and for which their private or public insurance is not reimbursing EMEND®, will continue to receive supply from the program until the end of their current chemotherapy treatment.

The compassionate provision of aprepitant has been transferred to **Merck Frost® Patient Assistance Program** that is now open for enrolment of new patients. Compassionate supply of drug is available based on financial need. No co-pay or financial assistance is offered by the program at this time. For further information on the program or to enrol a new patient, please contact **Merck Frosst® Patient Assistance Program** at 1-866-906-3725. The drug is currently not covered by PharmaCare and new patients starting on aprepitant would need to cover the cost themselves.

FOCUS ON MEDICATION MISADVENTURES

Patient safety has been an increasing focus in both Canada and the US. For example, patient safety was a focal point of the recent BCCA accreditation by Accreditation Canada (www.accreditation.ca/knowledge-exchange/patient-safety/goals). In 2003, the Canadian government established the Canadian Patient Safety Institute (www.patientsafetyinstitute.ca) to build and advance a safer healthcare system. Preventing medication misadventures is an important component in ensuring patient safety. One of the ways we, as individuals and healthcare organizations, can minimize potential medication misadventures is to foster a culture of safety. Talking about our concerns, near misses or 'good catches' is a great way to heighten our general awareness and help prevent problems in the future.

The following incidents have occurred in BC and highlight the real possibility of drug-to-drug interactions adversely affecting patients who are on phenytoin (DILANTIN®) and subsequently are started on chemotherapy with capecitabine or fluorouracil.

Medication Misadventure #1:

This patient was on chronic oral phenytoin for seizure control, prescribed and monitored by the family doctor. She was subsequently started on capecitabine for breast cancer (BRAVCAP protocol). The pharmacist noted that there was a potential for a drug-to-drug interaction and communicated this to the family doctor by fax. Unfortunately that faxed memo did not reach the family doctor for unknown reasons.

Two weeks later, the patient started to feel unwell, with sensory impairment and nausea. A STAT phenytoin level was requested and reported as critically high at 171 μ mol/L (usual range 40-80 μ mol/L). The phenytoin dose was adjusted and phenytoin levels were monitored, with close observation at home and medical surveillance. Her symptoms resolved and chemotherapy was safely continued.

Medication Misadventure #2:

This patient was on oral phenytoin and subsequently started on fluorouracil and irinotecan (GIFOLFIRI protocol) for colorectal cancer in February, 2009. Prior to the third cycle of chemotherapy, she reported feelings of depression, anxiety and trembling to her oncologist. The physician noted that the patient was on phenytoin for a seizure disorder which developed during prior treatment with paroxetine for depression. The patient was referred to Patient and Family Counselling (P&FC) for her depressive symptoms. On March 22nd, the patient contacted the on-call medical oncologist because she felt emotionally unwell and she was considering stopping her chemotherapy as she was unable to cope with the symptoms she was experiencing. The oncologist asked the patient to see her family doctor and P&FC at the BC Cancer Agency.

The patient reported the following symptoms to P&FC: leg weakness, trembling in face/hands, depression, and emotional distress. The patient was referred to emergency psychiatry services. Two days later, the family doctor contacted the covering oncologist to relay these symptoms, as the oncologist in charge was not available. A STAT phenytoin level was requested and reported to be critically high at 173 μ mol/L. The patient was admitted to hospital for hydration and medical surveillance. Her phenytoin dose was titrated and two weeks later the patient was reported to have therapeutic phenytoin levels and to be symptom free.

Take Home Message:

There is a potential risk of a drug-to-drug interaction between phenytoin and fluorouracil/capecitabine. These two patients likely had a drug-to-drug interaction which was undetected until they experienced a critical phenytoin level and symptoms of phenytoin toxicity. Health care providers need to be aware of this possibility, ensure appropriate monitoring of phenytoin blood levels, and patients need to be aware of symptoms to report (e.g., i.e. hypotension, psychiatric changes, dizziness, bradycardia, drowsiness, headaches, insomnia, rash, nausea, vomiting). Symptoms related to toxicity need to be promptly addressed.

CANCER DRUG MANUAL

Lanreotide Monograph and **Patient Handout** have been developed. Expert review was provided by Dr. Ehud Ur (Endocrinologist, St. Paul's Hospital). Lanreotide is a synthetic analogue of somatostatin, similar to octreotide. BCCA Compassionate Access Program (CAP) approval will need to be obtained prior to use. Highlights of the new monograph include:

 most commonly reported side effects include bradycardia, loss of glucose control (hyper- or hypoglycemia), and cholelithiasis

- absorption of oral medications may be altered
- after the first three injections, adjustments to dose are made in response to symptoms and growth hormone (GH) and insulin-like growth factor (IGF)-1 levels

Highlights of the new handout include:

symptoms of possible gall stones

Panitumumab Monograph and **Patient Handout** have been developed. Expert review was provided by Dr. Sanjay Rao (GI Tumour Group). Panitumumab is a fully human monoclonal antibody which binds to the human epidermal growth factor receptor (EGFR).

Highlights of the monograph include:

- monitor for hypomagnesemia, hypokalemia, and hypocalcemia before, during, and for eight weeks
 after treatment; symptoms may include severe weakness and fatigue
- dermatologic toxicities are reported in 91-95% of patients but are usually mild to moderate in severity; grade 3 or 4 reactions are reported in 5-16%.
- routine premedication is not required because severe infusion reactions are uncommon (1% incidence) compared to other monoclonal antibody therapies
- monitor for renal failure in patients developing severe diarrhea and dehydration; panitumumab should be held until recovery
- patients over 65 may experience an increased incidence of side effects that may lead to decisions to permanently discontinue the treatment

Highlights of the handout include:

- skin reactions can be exacerbated by sunlight: avoid direct sunlight and tanning salons; appropriate use
 of sunscreens is recommended
- persistent diarrhea, especially if accompanied by signs of dehydration, should be reported immediately to the physician

Rituximab Monograph has been updated to include a revised statement about observation following infusion, in response to changes in Lymphoma Tumour Group protocols. Except during the first dose, constant visual observation is no longer required as long as there has been no prior reaction.

Dasatinib Monograph has been updated to include the newly available 100 mg strength tablet.

Chemotherapy Preparation and Stability Chart has been updated:

- Panitumumab:
 - the presence of white particulates in the vials will not affect the quality of the product
 - use a 0.2 or 0.22 micron low protein binding in-line filter for administration
- Gemcitabine: information for Novopharm brand product has been added

COMMUNITIES ONCOLOGY NETWORK

Seventh National Summit on Community Cancer Control Approximately 400 delegates gathered in Prince George for this national conference hosted by the Northern Health Authority on June 11-13, 2009. Community Cancer Summits are held every two or more years and are attended by healthcare professionals, volunteers, policy makers, survivors and caregivers from across Canada and the US. These summits provide opportunities for sharing ideas for workable solutions to common rural and community cancer control issues.

To support this event, the BC Cancer Agency amalgamated its annual care conference with the Summit for this year. Instead, a BC Cancer Agency Professional Education Day was held on the first day of the

Summit. Learning events were held by five specialty groups: nursing, nutrition, oral oncology, pain and symptom management and psychosocial oncology.

The theme of the Summit, "Innovative Solutions for Rural and Remote Cancer Control Issues: Today and Tomorrow", was addressed by about 90 experts who shared ideas in embracing today's healthcare challenges. To encourage dissemination and discussion of these ideas, a number of these presentations are available on the Summit website (www.cancersummit.ca).

The BC Cancer Agency also supported the Summit with staff who spoke for the Community Cancer Control portion of the conference. This included a discussion by Sandra Broughton, Marianne Taylor and Marilyn Porter on their experience in starting a Telemedicine program at the Centre for the Southern Interior (CSI). Oncologists from CSI started seeing patients from remote locations by video link, to address the shortage of physicians in these remote locations. Janice MacDonald, a nurse from the Kamloops Cancer Clinic, explained how well received Telemedicine has been by patients. They most often preferred the option of seeing a physician quickly by video link rather than waiting a longer period of time to meet with a physician face to face.

The importance of sharing ideas and information was emphasized during presentations on the intravenous-pump programming error that occurred in Alberta. The error led to the infusion of four days' worth of fluorouracil over four hours, causing the death of a patient. Tony Fields, the vice president of the Cancer Corridor division of Alberta Health Services, detailed the steps that Alberta Health took to respond to this incidence. At the time, the Alberta Cancer Board went public with information about the event, to help prevent similar incidence in the future. Investigations revealed that seven similar errors had occurred in the past, but none of them were widely shared with the public. Rachel White, a human factors specialist, described the multiple factors involved in this error and outlined how procedures were often set up in ways that could contribute to human error. Therefore, she has been helping the training of staff to spot procedures that contribute to errors and make changes to improve safety.

Another method for sharing ideas that was discussed at the Summit is the "Service Delivery Models Project" by the Health Human Resources Action Group of the Canadian Partnership Against Cancer (CPAC). This project involves the development of a searchable database of greater than 100 innovative service delivery models of cancer control. Information about this project is located on the CPAC website at www.partnershipagainstcancer.ca/hhr_service. If you have an innovative idea for providing cancer care that you would like to share, please contact Jo Ann Miller (jamiller@hollanderanalytical.com).

Submitted by: Rhonda Kalyn, BSP Pharmacy CON Educator Centre for the Southern Interior – BC Cancer Agency

BENEFIT DRUG LIST

The following new program has been funded by the Provincial Systemic Therapy Program effective 1 August 2009:

Cetuximab and Irinotecan as third line treatment for patients whose metastatic colorectal cancer is no
longer responding to fluorouracil, irinotecan and oxaliplatin, and whose tumour has been shown to be
of wild type KRAS (UGIAVCETIR).

This new indication is added to the benefit list and a BCCA "Compassionate Access Program" request with appropriate clinical information for each patient must be approved prior to treatment.

LIST OF NEW AND REVISED PROTOCOLS, PRE-PRINTED ORDERS AND PATIENT HANDOUTS

BC Cancer Agency Protocol Summaries, Provincial Pre-Printed Orders (PPPOs) and Patient Handouts are revised periodically. New and revised protocols, PPPOs and patient handouts for this month are listed below. Protocol codes for treatments requiring "Compassionate Access Program" (previously Undesignated Indication Request) approval are prefixed with the letter **U**.

NEW protocols, PPPOs and Patient Handouts (Affected Documents are Checked):

CODE	Protocol	PPPO	Patient Handout	Protocol Title
UCNTEMOZMD		$\overline{\mathbf{V}}$		Therapy for Malignant Brain Tumours Using Dose-Dense Temozolomide
UGIAVCETIR	\square			Third Line Treatment of Metastatic Colorectal Cancer Using Cetuximab in Combination with Irinotecan
UGIAVPG	\square	V		First-line Palliative Chemotherapy for Advanced Pancreatic Adenocarcinoma, Gallbladder Cancer and Cholangiocarcinoma using Gemcitabine and Cisplatin
UGIRAJFFOX			\square	Adjuvant combination chemotherapy for stage III rectal cancer using Oxaliplatin, 5-Fluorouracil and Folinic Acid (Leucovorin)
UGIAJFFOX			\square	Adjuvant combination chemotherapy for stage III colon cancer using Oxaliplatin, 5-Fluorouracil and Folinic Acid (Leucovorin)
UGIFOLFOX			\square	Combination chemotherapy for metastatic cancer of the colon or rectum using Oxaliplatin, 5-Fluorouracil and Folinic Acid (Leucovorin)
HNLANPRT			V	Summary for Treatment of Locally Advanced Nasopharyngeal Cancer with Concurrent Cisplatin and Radiation

REVISED PROTOCOLS, PPPOS AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED):

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
BRAJACTT	$\overline{\mathbf{A}}$			Eligibility clarified	Adjuvant Therapy for Breast Cancer using Doxorubicin and Cyclophosphamide followed by Paclitaxel and Trastuzumab
BRAJACTTG	V			Eligibility clarified	Adjuvant Therapy for Breast Cancer Using Dose Dense Therapy: Doxorubicin and Cyclophosphamide Followed by Paclitaxel and Trastuzumab
BRAJCMF	V			Timing of radiation clarified	Adjuvant Therapy of High Risk Breast Cancer using Cyclophosphamide, Methotrexate and Fluorouracil
BRAJCMFPO				Timing of radiation clarified	Adjuvant Therapy for High-Risk Breast Cancer using Cyclophosphamide (oral), Methotrexate and Fluorouracil
BRAJFECD	V			Minor typo corrected in numbering of Dose Modifications	Adjuvant Therapy for Breast Cancer Using Fluorouracil, Epirubicin and Cyclophosphamide and Docetaxel

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
BRAJTR				Minor typo corrected in Treatment section	Adjuvant Therapy for Breast Cancer using Trastuzumab (HERCEPTIN®) following the Completion of Chemotherapy (Sequential)
CNTEMOZ	V	V		Unsafe symbol replaced in Renal dysfunction section in protocol, imaging clarified in PPPO	Therapy for Malignant Brain Tumours Using Temozolomide
UGIAJFFOX	V			Antiemetics clarified, optional calcium and magnesium therapy added, drug interactions added to Precautions	Adjuvant Combination Chemotherapy for Stage III Colon Cancer Using Oxaliplatin, 5- Fluorouracil and Folinic Acid (Leucovorin)
GIAVCAP	V	V		CAP approval for additional cycles added; options added for repeat prescriptions and return to clinic appointment to PPPO	Palliative Therapy of Advanced Colorectal Cancer using Capecitabine
GIAVFL	V			Timing of blood chemistry revised, option of leucovorin 20 mg/m2 added, drug interaction added to Precautions; option to return to clinic added to PPPO	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using 5- Fluorouracil Injection and Infusion and Folinic Acid (Leucovorin) Infusion
UGIAVPANI	V			Contact information revised, reminder of only one option of anti- EGFR therapy funded	Palliative Third Line Treatment of Metastatic Colorectal Cancer Using Panitumumab
UGICAPIRI		Ø		Option to return to clinic added to PPPO	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Irinotecan and Capecitabine in Patients Unsuitable for GIFOLFIRI
UGICAPOX	V	V		Antiemetics clarified; option to return to clinic added to PPPO	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Oxaliplatin, and Capecitabine
UGICIRB	Ø			Baseline tests clarified, bevacizumab infusion time shortened; option to return to clinic added to PPPO	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Irinotecan, Bevacizumab and Capecitabine
UGICOXB	V	$\overline{\mathbf{A}}$		Baseline tests and antiemetics clarified, bevacizumab infusion time shortened; option to return to clinic added to PPPO	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Oxaliplatin, Bevacizumab and Capecitabine

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
UGIFFIRB	V			Baseline tests clarified, bevacizumab infusion time shortened, option of leucovorin 20 mg/m2 added, drug interaction added to Precautions	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Irinotecan, Fluorouracil, Folinic Acid (Leucovorin) and Bevacizumab
UGIFFOXB	V	V		Baseline tests and antiemetics clarified, bevacizumab infusion time shortened, option of leucovorin 20 mg/m2 added, drug interactions added to Precautions; option to return to clinic added to PPPO	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Oxaliplatin, 5-Fluorouracil, Folinic Acid (Leucovorin) and Bevacizumab
GIFOLFIRI	V	Ø		Timing of blood chemistry revised, option of leucovorin 20 mg/m2 added, CAP approval for additional cycles added; option to return to clinic added to PPPO	First Line Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Irinotecan, Fluorouracil and Folinic Acid (Leucovorin)
UGIFOLFOX	V			Antiemetics clarified, timing of blood chemistry revised, option of leucovorin 20 mg/m2 added, drug interaction added to Precautions; option to return to clinic added to PPPO	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Oxaliplatin, 5-Fluorouracil and Folinic Acid (Leucovorin)
GIFUC		$\overline{\mathbf{A}}$		Option to return to clinic added to PPPO	Palliative Chemotherapy for Upper Gastrointestinal Tract Cancer (Gastric, Esophageal, Gall Bladder Carcinoma and Cholangiocarcinoma) and Metastatic Anal Cancer using Infusional Fluorouracil and Cisplatin
GIGAIRT				Instructions for patient's premedications clarified	Combined Modality Adjuvant Therapy for Completely Resected Gastric Adenocarcinoma using Fluorouracil + Folinic Acid (Leucovorin) and Radiation Therapy.
GIGAVECF	V	Ø		Scheduling of lab tests clarified, drug interactions added to Precautions	Palliative Therapy for Metastatic or Locally Advanced Gastric, Esophagogastric Cancer Using Epirubicin, Cisplatin and Infusional Fluorouracil
GIGECF	V	V		Scheduling of lab tests clarified, drug interactions added to Precautions	Perioperative Treatment of Resectable Adenocarcinoma of the Stomach, Gastroesophageal Junction or Lower 1/3 Esophagus using Epirubicin, Cisplatin and Infusional Fluorouracil
UGIRAJFFOX	V			Optional calcium and magnesium therapy added, drug interactions added to Precautions	Adjuvant Combination Chemotherapy for Stage III Rectal Cancer Using Oxaliplatin, 5-Fluorouracil and Folinic Acid (Leucovorin)

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
UGISORAF		V		Timing of urinalysis and bloodwork revised	Therapy for Advanced Hepatocellular Carcinoma Using Sorafenib (NEXAVAR®)
GOOVGEM		Ø		Scheduling of bloodwork clarified	Palliative chemotherapy for re-treatment of ovarian, tubal, and peritoneal cancer using gemcitabine
GUPDOC	V			Number of treatment cycles revised	Palliative Therapy for Metastatic Hormone Refractory Prostate Cancer Using Docetaxel
UGUSORAF		V		Timing for bloodwork revised	Palliative Therapy for Renal Cell Carcinoma Using Sorafenib (NEXAVAR®)
UGUSUNI		Ø		Timing for bloodwork revised	Palliative Therapy for Renal Cell Carcinoma Using Sunitinib
HNLANPRT	V			Cisplatin administration and hydration revised	Summary for Treatment of Locally Advanced Nasopharyngeal Cancer with Concurrent Cisplatin and Radiation
HNPE	V			Clarification of bloodwork scheduling	Intensive Cisplatin and Etoposide Chemotherapy for Recurrent and Metastatic Head and Neck Cancer
ULKMDSL	Ø			Clarification of bloodwork monitoring	Therapy of Myelodysplastic Syndrome using Lenalidomide
LUAVERL	\square			Eligibility clarified, toxicity information updated in Precautions	Treatment of Advanced Non-Small Cell Lung Cancer (NSCLC) with Erlotinib
LUAVPEM				Eligibility revised with additional histology information	Second-Line Treatment of Advanced Non-Small Cell Lung Cancer (NSCLC) With Pemetrexed
UMYLENDEX	V		V	Clarification of eligibility, exclusions, bloodwork, dosing, monitoring; pharmacist counselling, RevAid procedures, instruction of administration clarified	Therapy of Multiple Myeloma Using Lenalidomide with Dexamethasone
LUMMPP	\square			Premedications clarified	Treatment of Malignant Mesothelioma with Platinum and Pemetrexed
USAAVGS		V		Timing for bloodwork revised	Second Line Treatment of Advanced C-kit Positive Gastrointestinal Stromal Cell Tumours (GIST's) After Imatinib Using Sunitinib (SUTENT®)

WEBSITE RESOURCES

The following are available on the BC Cancer Agency website (www.bccancer.bc.ca) under the Health Professionals Info section:

REIMBURSEMENT AND FORMS: BENEFIT DRUG LIST,	www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Forms		
CLASS II, BC CANCER AGENCY COMPASSIONATE			
ACCESS PROGRAM (UNDESIGNATED INDICATION)			
CANCER DRUG MANUAL	www.bccancer.bc.ca/cdm		
CANCER MANAGEMENT GUIDELINES	www.bccancer.bc.ca/CaMgmtGuidelines		
CANCER CHEMOTHERAPY PROTOCOLS, PRE-PRINTED	www.bccancer.bc.ca/ChemoProtocols		
ORDERS AND PROTOCOL PATIENT HANDOUTS			
Systemic Therapy Program Policies	www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Policies		
SYSTEMIC THERAPY UPDATE	www.bccancer.bc.ca/HPI/ChemotherapyProtocols/stupdate		
COMPLEMENTARY AND ALTERNATIVE CANCER THERAPIES	under Patient/Public Info, Complementary Therapies		

Editorial Review Board

Mário de Lemos, PharmD, MSc (Oncol) (Editor) Victoria Kyritsis, MSc (Clin Pharm) (Assistant Editor) Caroline Lohrisch, MD Johanna Den Duyf, MA Judy Oliver, BScN, MEd Beth Morrison, MLS Jaya Venkatesh, MHA, CMA Susan Walisser, BSc (Pharm)

In Touch	www.bccancer.bc.ca	bulletin@bccancer.bc.ca
BC CANCER AGENCY		
	(604) 877-6000	* *
PROVINCIAL SYSTEMIC THERAPY PROGRAM		
COMMUNITIES ONCOLOGY NETWORK	Ext 2744	jvenkate@bccancer.bc.ca
UPDATE EDITOR	Ext 2288	mdelemos@bccancer.bc.ca
COMMUNITIES ONCOLOGY NETWORK PHARMACIST	Evt 6277	lourelle@beconger be ea
COMMUNITIES ONCOLOGY NETWORK PHARMACY EDUCATORS		
0	F. (0077	yNetwork/Educators/Pharmacists/
COMPASSIONATE ACCESS PROGRAM OFFICE		cap_bcca@bccancer.bc.ca
Doug Incornation	Fax (604) 708-2026 Ext 6275	drugints@bassassr.ba.sa
DRUG INFORMATION		
EDUCATION RESOURCE NURSE		
NURSING PROFESSIONAL PRACTICE	Ext 2623	ilundie@bccancer.bc.ca
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OSCAR HELP DESK	1-(888)-355-0355	oscar@bccancer.bc.ca
	Fax (604) 708-2051	
PHARMACY PROFESSIONAL PRACTICE	(250) 519.5574	jkippen@bccancer.bc.ca
ABBOTSFORD CENTRE (AC)	(604) 851-4710	Toll-free: 1-(877) 547-3777
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VANCOUVER CENTRE (VCC)	(604) 877-6000	Toll-Free 1-(800) 663-3333
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