



BC Cancer Agency

CARE + RESEARCH

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Systemic Therapy Update

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For Health Professionals Who Care For Cancer Patients

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EDITOR'S CHOICE

NEW PROGRAMS

The Provincial Systemic Therapy Program has approved the following program effective 01 April 2014:

Gynecology:

Bevacizumab in Combination with Carboplatin and Paclitaxel for Primary Treatment of Metastatic/Recurrent Squamous Cancer of the Cervix (UGOCXCATB) – The BCCA Gynecology Tumour Group recommends adding bevacizumab to the previous standard platinum-doublet containing carboplatin and paclitaxel (GOCXCAT) in all patients with recurrent or metastatic squamous cervical cancer, unless contraindicated. In a phase III, open-label randomized trial comparing two platinum-doublet based chemotherapy regimens alone to the same plus bevacizumab in previously untreated metastatic cervical cancer, bevacizumab was associated with superior median overall survival (mOS) (17.0 mo vs. 13.3 mo, HR 0.71, 98% CI 0.54-0.95), and median progression free survival (mPFS) (8.2 mo vs. 5.9 mo, HR 0.67, 95% CI 0.54-0.82). [Tewari KS, et al. NEJM 2014;370:734-743] On subgroup analysis, the benefit of treatment was entirely confined to the squamous histology (adenosquamous and adenocarcinoma did not benefit). Compared to chemotherapy alone, bevacizumab was associated with increased rates of hypertension of grade 2 or higher (25% vs. 2%), gastrointestinal or genitourinary fistulas of grade 3 or higher (6% vs. 0%), and thromboembolic events of grade 3 or higher (8% vs. 1%). Hence, patients with uncontrolled hypertension, major surgery within 4 weeks, or uncontrolled arterial or venous thromboembolism should be considered for treatment without bevacizumab (i.e. GOCXCAT).

PROVINCIAL SYSTEMIC THERAPY PROGRAM

B.C. RESIDENT PATIENT REFERRALS FOR CANCER TREATMENT IN OTHER PROVINCES AND TERRITORIES

B.C. residents are sometimes referred out-of-province for cancer treatment due to geographic or personal reasons. This may present some financial challenges regarding medication coverage for patients. The following considerations may help reduce financial strain incurred by cancer patients who are being treated outside B.C.:

- All B.C. residents for whom cancer drug reimbursement is required MUST be registered with the BCCA, even if referred for out-of-province treatment. Clinicians may call 1-800-663-3333 (Ext. 674610) to obtain a registration form.
- BCCA-funded cancer regimens being delivered out-of-province are eligible for reimbursement according to the information outlined in Table 1. All BCCA-funded cancer regimens can be found on the BCCA Benefit Drug List at: <http://www.bccancer.bc.ca/HPI/CancerTherapyProtocols/Forms.htm>.
- If treatment delivered outside B.C. is not provided according to a BCCA-funded cancer regimen, it must receive BCCA Compassionate Access Program (CAP) approval PRIOR to the start of treatment. Please contact the CAP office via email (cap_bcca@bccancer.bc.ca) or phone (1-800-663-3333 [Ext. 672676]) for assistance.

Table 1. BCCA reimbursement information for cancer treatment delivered outside B.C.

Parenteral Chemotherapy	Oral Chemotherapy & Other Take-Home Cancer Medications	Supportive Care Medications
<ul style="list-style-type: none">▪ Providing that BCCA patient registration and funding criteria are met, parenteral chemotherapy is funded through inter-provincial reciprocity agreements.▪ B.C. resident patients do not usually need to self-pay and seek reimbursement from the BCCA for parenteral chemotherapy drugs delivered outside of B.C.	<ul style="list-style-type: none">▪ Depending on the province/territory providing treatment, patients may be asked to self-pay for oral chemotherapy and other take-home cancer medications, and to seek reimbursement from the BCCA.▪ Providing that BCCA patient registration and funding criteria are met, the BCCA will reimburse up to the equivalent drug cost at the BCCA.▪ Reimbursement generally takes up to 6-8 weeks, but delays may occur.▪ In some cases, patients may have unrecoverable expenses due to drug price differences between the BCCA & other provinces/territories.	<ul style="list-style-type: none">▪ Supportive care medications are not funded by the BCCA.▪ Patients should consult with BC PharmaCare and/or their own extended health insurance providers to determine if supportive care medications purchased outside B.C. will be covered.▪ For patients registered with the BC Financial Support Drug Program (FSDP), FSDP does not provide financial coverage for supportive care medications purchased outside B.C.

CHANGES TO THE FINANCIAL SUPPORT DRUG PROGRAM (FSDP) DRUG BENEFIT LIST

The Financial Support Drug Program (FSDP) is funded and operated by the BCCA Provincial Systemic Therapy Program. Through a partnership with the Canadian Cancer Society, more than 500 cancer patients in BC were approved in 2013 to receive financial assistance for the coverage of supportive care medications specified under the FSDP Drug Benefit List.

PROVINCIAL SYSTEMIC THERAPY PROGRAM

Effective 01 April 2014, the following changes to the FSDP Drug Benefit List are being implemented:

1. Non-prescription drugs (e.g. over-the-counter medications) will no longer be benefits of the FSDP.
2. The FSDP will no longer approve non-benefit medications on a case-by-case basis.

Please note that previously authorized non-prescription or non-benefit list drugs will continue to be honoured for the approved duration or until the end of the patient's FSDP benefit year, whichever comes first. However, these items will not be re-authorized thereafter. Also, requests from physicians for additions to the FSDP Drug Benefit List will still be considered. Requests can be made via email at BCCA_eap@bccancer.bc.ca.

The above changes align with FSDP's mandate to assist patients to access supportive care medications currently recommended in the BCCA treatment protocols, to focus on prescription medications recommended by medical & radiation oncology, as well as prescription analgesics and co-analgesics recommended by the Pain & Symptom Management team. These changes will also allow more expensive prescription supportive care medications to be added to the FSDP Drug Benefit List. The goal is to increase patient access to supportive care medications needed to facilitate the completion of their cancer treatment.

For additional information about the FDSP, please see the BCCA website at:

<http://www.bccancer.bc.ca/RS/CommunitiesOncologyNetwork/Emergency+Aid+Drug+Program/default.htm>

DRUG UPDATE

UPDATE: INTRAMUSCULAR VITAMIN B12 Now AVAILABLE

After several months of intermittent drug shortages across the country, the parental formulation of vitamin B12 injectable for intramuscular (IM) administration is now available, and no longer on supply allocation. Patients on pemetrexed-containing treatment protocols (LUAVPEM, ULUAVPMTN, ULUAVPP, LUMMPP) may now access IM vitamin B12 to minimize pemetrexed-associated hematologic toxicities as per protocol instructions.

CANCER DRUG MANUAL

NEW MONOGRAPHS AND PATIENT HANDOUTS

Crizotinib Monograph and Patient Handout have been completed. Expert review was provided by Dr. Barb Melosky (Medical Oncologist), and Rose-Marie Reddy and Alysha Bharmal (Pharmacists) of the BCCA Lung Tumour Group. Crizotinib is indicated for the treatment of ALK-positive advanced non-small cell lung cancer (ULUAVCRIZ). It is an oral, small molecule tyrosine kinase inhibitor which inhibits anaplastic lymphoma kinase (ALK) and hepatocyte growth factor receptors (HGFR or c-MET). Apoptosis is induced in tumour cell lines exhibiting ALK fusion events or ALK or MET gene amplification. The usual oral dose is 250 mg twice daily, administered with food or on an empty stomach. Vision disorders, including blurry or

CANCER DRUG MANUAL

double vision, are commonly reported. Patients should be cautioned as visual disturbances may affect their ability to drive or operate machinery. Rare, but potentially serious, side effects include symptomatic bradycardia, QT prolongation, pneumonitis and fatal hepatotoxicity. Cardiac and respiratory function should be assessed in patients with known risk factors, and hepatic function should be monitored throughout treatment.

REVISED MONOGRAPHS AND PATIENT HANDOUTS

Highlights of key changes and/or updates to the Monographs and Patient Handouts are listed below:

Bexarotene:

- **Monograph and Handout:**
 - *Interactions* – the grapefruit interaction has been deleted as the clinical significance of this theoretical interaction is unknown; more details are provided on the Monograph below the Interactions table.
 - *Supply and Storage* – storage instructions on the Monograph have been revised to 2-25°C based on manufacturer's recommendations; patients are recommended on the Handout to store product at room temperature as refrigeration is considered unnecessary.

Busulfan:

- **Monograph and Handout:**
 - *Interactions* – the grapefruit interaction has been deleted as available evidence on the metabolic pathway does not support this interaction.

Estramustine:

- **Monograph and Handout:**
 - *Supply and Storage* – storage instructions on the Monograph have been revised to 2-25°C based on manufacturer's recommendations; patients are recommended on the Handout to store product at room temperature as refrigeration is considered unnecessary.

Flutamide:

- **Monograph and Handout:**
 - *Interactions* – the grapefruit interaction has been deleted as the clinical significance of this theoretical interaction is unknown; more details are provided on the Monograph below the Interactions table.

Gefitinib:

- **Monograph:**
 - *Interactions* – included new information on the relationship between dose and exposure in the grapefruit interaction.

Lapatinib:

- **Monograph & Handout:**
 - *Interaction* – added esomeprazole interaction.

BENEFIT DRUG LIST

NEW PROGRAMS

The following program has been added to the [Benefit Drug List](#) effective 01 April 2014:

Protocol Title	Protocol Code	Benefit Status
Primary Treatment of Metastatic/Recurrent Squamous Cancer of the Cervix with Bevacizumab, CARBOplatin and PACLitaxel	UGOCXCATB	Restricted

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, revised or deleted protocols, PPPOs and patient handouts for this month are listed below. Protocol codes for treatments requiring “Compassionate Access Program” (previously Undesignated Indications 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
UGOCXCATB	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Primary Treatment of Metastatic/Recurrent Squamous Cancer of the Cervix with Bevacizumab, CARBOplatin and PACLitaxel

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

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
BRAJACTT	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Treatment section reformatted for clarity</i>	Adjuvant Therapy for Breast Cancer using DOXOrubicin and Cyclophosphamide followed by PACLitaxel and Trastuzumab
UBRAVPTRAD	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Treatment section reformatted for clarity</i>	Palliative Therapy for Metastatic Breast Cancer Using Pertuzumab, Trastuzumab, and DOCEtaxel as First-Line Treatment for Advanced Breast Cancer
UGIYTT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Eligibility updated</i>	Yttrium-90 for Transarterial Radioembolisation (TARE)
GOOVCA	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Treatment section reformatted for clarity</i>	Treatment of Advanced Ovarian Cancer in Patients Who Have Progressed or Recurred Following First-line Platinum-Based Treatment Using CARBOplatin and Gemcitabine
GOOVDDCAT	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Treatment section reformatted for clarity</i>	Treatment Of Advanced Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Carcinoma Using CARBOplatin and Weekly PACLitaxel

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

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
GUNAJPG	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Cisplatin infusion time clarified</i>	Neo-Adjuvant Therapy for Urothelial Carcinoma Using CISplatin and Gemcitabine
HNSAVNP	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Vinorelbine infusion time clarified</i>	Treatment of Advanced Salivary Gland Cancers With CISplatin and Vinorelbine
LYFLUDR	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Indication clarified</i>	Treatment of Chronic Lymphocytic Leukemia or Prolymphocytic Leukemia with Fludarabine and riTUXimab
SAAVGEMD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Title and Eligibility clarified, references added</i>	Therapy for Soft Tissue Sarcomas using Gemcitabine and DOCETaxel

WEBSITE RESOURCES AND CONTACT INFORMATION

WEBSITE RESOURCES	
Systemic Therapy Update	www.bccancer.bc.ca/HPI/ChemotherapyProtocols/stupdate
Reimbursement & Forms: Benefit Drug List, Class II, Compassionate Access Program	www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Forms
Cancer Drug Manual	www.bccancer.bc.ca/cdm
Cancer Management Guidelines	www.bccancer.bc.ca/CaMgmtGuidelines
Cancer Chemotherapy Protocols, Pre-printed Orders, Protocol Patient Handouts	www.bccancer.bc.ca/ChemoProtocols
Systemic Therapy Program Policies	www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Policies
CON Pharmacy Educators	http://www.bccancer.bc.ca/HPI/Pharmacy/ContactUs.htm

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To update the contact information of any CON sites, please contact:			bulletin@bccancer.bc.ca
Oncology Drug Information	604.877.6275		druginfo@bccancer.bc.ca
Education Resource Nurse	604.877.6000 x 672638		nursinged@bccancer.bc.ca
Library/Cancer Information	604.675.8003 Toll Free 888.675.8001 x 8003		requests@bccancer.bc.ca
Pharmacy Professional Practice	250. 519.5574		jkippen@bccancer.bc.ca
Nursing Professional Practice	604.877.6000 x 672623		ilundie@bccancer.bc.ca
OSCAR	888.355.0355	604.708.2051	oscar@bccancer.bc.ca
Compassionate Access Program (CAP)	604.877.6277	604.708.2026	cap_bcca@bccancer.bc.ca
Pharmacy Chemotherapy Certification	250.712.3900 x 686741		rxchemocert@bccancer.bc.ca
BCCA-Abbotsford Centre	604.851.4710 Toll Free 877.547.3777		
BCCA-Centre for the North	250.645.7300 Toll Free 888.775.7300		
BCCA-Fraser Valley Centre	604.930.2098 Toll Free 800.523.2885		
BCCA-Sindi Ahluwalia Hawkins Centre for the Southern Interior	250.712.3900 Toll Free 888.563.7773		
BCCA-Vancouver Centre	604.877.6000 Toll Free 800.663.3333		
BCCA-Vancouver Island Centre	250.519.5500 Toll Free 800.670.3322		

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