



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 programs effective 01 December 2013:

Breast:

Everolimus with Exemestane for Postmenopausal Women with Metastatic ER-Positive, HER2-Negative Breast Cancer (BRAVEVEX) – Patients are eligible for this new treatment if their disease has relapsed or progressed after the use of a non-steroidal aromatase inhibitor (AI) (anastrozole, letrozole). Evidence for everolimus with exemestane in this patient population is based on a phase III trial (Bolero II Study) that demonstrated superior median progression free survival (PFS) (10.6 mo vs. 4.1 mo, HR 0.36 [95% CI 0.27-0.47]). [Baselga et al. *NEJM* 2012;366:520-529] Overall survival (OS) data were not yet mature at the time of reporting. Everolimus is an inhibitor of mTOR (mammalian target of rapamycin), which plays an essential role in protein synthesis downstream of the P13K/AKT pathway, resulting in reduced cell proliferation, glycolysis and angiogenesis of solid tumours. Common toxicities include stomatitis, fatigue, rash, diarrhea, hyperglycemia and a small incidence of symptomatic pneumonitis. Everolimus also exerts immunosuppressive effects, and has been associated with infections in up to 37% of patients.

EDITOR'S CHOICE

Everolimus received the Health Canada Notice of Compliance for this particular indication in January 2013. Eligible patients were granted access to the drug through the manufacturer's AfiniTRAC Reimbursement Support Program. Patients who were enrolled in this program prior to 01 December 2013 will continue to access everolimus via the same.

Genitourinary:

Palliative Therapy for Metastatic Castration Resistant Prostate Cancer (mCRPC) Using Enzalutamide (UGUPENZ) – The Genitourinary Tumour Group has approved enzalutamide as an alternative treatment to abiraterone or cabazitaxel for patients with symptomatic mCRPC who have received prior docetaxel-containing chemotherapy. Program approval was based on a phase III trial (AFFIRM Study) involving 1199 men with mCRPC who were previously treated with chemotherapy, and randomized to enzalutamide or placebo. [Scher et al. *NEJM* 2012;367:1187-1197] At the planned interim analysis, enzalutamide was associated with significant improvement in median OS (18.4 mo vs. 13.6 mo, HR 0.63 [95% CI 0.53-0.75]), and radiologic PFS (8.3 mo vs. 2.9 mo, HR 0.40 [95% CI 0.35-0.47]). Enzalutamide was associated with higher rates of fatigue, diarrhea and hot flashes compared to the control arm. More information about enzalutamide can be found in the [Cancer Drug Manual](#) section below.

Effective 01 December 2013, enzalutamide treatment will be covered by:

1. BCCA:
 - For all new patients who meet the UGUPENZ eligibility criteria
 - For patients who had previously obtained private insurance coverage for enzalutamide, and meet the UGUPENZ eligibility criteria
2. Manufacturer's XTANDI® Patient Assistance Program:
 - For all patients who had enrolled in this program prior to 01 December 2013

Please note that patients who had received enzalutamide via the XTANDI® Patient Assistance Program or private insurance are not eligible for subsequent BCCA-funded abiraterone or cabazitaxel treatment. Sequential treatment using any of the following agents for mCRPC is not approved by the BCCA – enzalutamide, abiraterone, cabazitaxel.

MEDICATION SAFETY CORNER

REMINDER: TRASTUZUMAB – LOOK-ALIKE/SOUND-ALIKE MEDICATION ALERT

Effective 01 December 2013, all BCCA medication-related databases will include the generic and brand names for both trastuzumab (HERCEPTIN®) and trastuzumab emtansine (KADCYLA®) to reduce the risk for selection errors between the two drugs. Trastuzumab-containing chemotherapy protocols and pre-printed orders will also be updated to include the brand name (HERCEPTIN®) on a gradual basis over the next few months. For further information about this medication safety initiative, please see the [November 2013](#) issue of the Systemic Therapy Update.

BCCA DERS PUMP LIBRARY – REDUCTION IN AIR SENSITIVITY DETECTION SETTINGS

Effective 07 January 2014, the Dose Error Reduction Systems (DERS) Pump air sensitivity detection alert “default” settings will be reduced from the current setting of 500 mL to 250 mL to align with existing technical and clinical standards. Following an extensive review, it was determined that a decrease in detection threshold will reduce the risk of air embolism to the patient. This change will occur across all BCCA regional centres in both the Radiation Therapy and Systemic Therapy programs. Further communication and education will be provided to the BCCA nursing staff during December prior to the implementation of this change.

SAFETY UPDATE: ELASTOMERIC INFUSOR® RATE

Baxter Corporation issued a Safety Alert in September 2013 reminding healthcare providers to correctly follow the manufacturer instructions-for-use when operating the Elastomeric INFUSOR® device. This device is used to deliver continuous fluorouracil infusions at the BCCA. The alert stemmed from complaints of faster-than-intended infusion flow rates, potentially resulting in untoward toxicities and/or changes in treatment efficacy. Many cases of faster-than-intended infusion flow rates were the result of incorrect use.

The BCCA Pharmacy Communities Oncology Network (CON) Educators maintain a list of Frequently Asked Questions (FAQ) about Baxter Elastomeric INFUSORS® on the [BCCA Pharmacy](#) website. Topics addressed on the FAQ webpage include:

- Elastomeric INFUSOR® Checklist for Rate Error Prevention
- Elastomeric INFUSOR® Checklist for Identifying Causes of Rate Errors (previously published in the [December 2011](#) issue of the Systemic Therapy Update)
- How to deliver a 72-hour infusion

CONTINUING PROFESSIONAL DEVELOPMENT

CANADIAN BREAST CANCER SYMPOSIUM 2014

Date: February 21-22, 2014

Location: Fairmont Chateau, Whistler, BC

Early Bird Registration Deadline: 21 January 2014

Website: www.cdnbreastcancer.ca

This symposium will focus on the clinical application of molecular biology in the personalized care of breast cancer patients, and will review various areas of research.

BCCA EDUCATION PROGRAM FOR ONCOLOGY PHARMACISTS – NEW MODULES AVAILABLE

The [BCCA Education Program for Oncology Pharmacists](#) is a self-directed, freely accessible online program designed to support the knowledge development of pharmacists in a variety of oncology topics. Details about the program were previously described in the [August 2013](#) issue of the Systemic Therapy Update.

The following learning modules are available on the [Core Clinical Practice \(Level I\)](#) webpage, including the recent addition of three new modules:

Category	Learning Module
Chemotherapy Process	Chemotherapy Orders: Clinical Assessment and Review
	BCCA Website Navigation
Oncology Basics	CAPhO* Oncology Basics Module <i>*Canadian Association of Pharmacy in Oncology</i>
Cancer Management	Lung Cancer
	Colorectal Cancer (New)
	Prostate Cancer (New)
Monitoring and Diagnostics	Laboratory Monitoring (New)

Please contact the [CON Pharmacy Educators](#) if you have questions about the program.

CANCER DRUG MANUAL

NEW MONOGRAPHS AND PATIENT HANDOUTS

Enzalutamide Monograph, Patient Handout, and Hazardous Drug Evaluation have been completed, and expert review provided by Dr. Kim Chi from the BCCA Genitourinary Tumour Group. Enzalutamide is indicated for the treatment of metastatic castration-resistant prostate cancer. It is a competitive androgen receptor inhibitor which acts in the androgen receptor signaling pathway. It has greater affinity for androgen receptors than other anti-androgen agents, and lacks androgen receptor agonist activity in cell growth. The most common adverse reactions reported with enzalutamide include fatigue, hot flashes and headache. It is also associated with neuropsychiatric events (i.e. seizures, memory impairment, hallucinations), as well as QT-prolongation and hypertension. Review for CYP P450 drug interactions is recommended as enzalutamide is a substrate of CYP 2C8, a substrate and a strong inducer of CYP 3A4, and a moderate inducer of CYP 2C9 and CYP 2C19.

REVISED MONOGRAPHS AND PATIENT HANDOUTS

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

Bortezomib Monograph and Handout:

- *Interactions* – several interactions have been added (ascorbic acid, dexamethasone) and clarified (ketoconazole, rifampin)

Sunitinib Monograph:

- *Side Effects* – severe cutaneous reactions have been added in response to Health Canada alert. Cases of pyoderma gangrenosum, erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis have been rarely reported and are sometimes fatal.

CANCER DRUG MANUAL

TRANSLATION OF PATIENT INFORMATION

Translation of the following **Patient Handouts** are now available in Chinese and Punjabi:

- Carboplatin
- Cetuximab
- Chlorambucil
- Cisplatin
- Doxorubicin
- Gemcitabine
- Mitomycin (IV)
- Thioguanine

These documents are available on the [BCCA Drug Index \(Patient\)](#) webpage with the corresponding English versions. To learn more about this pilot project, please see the [September 2011](#) issue of the Systemic Therapy Update.

BENEFIT DRUG LIST

NEW PROGRAMS

The following programs have been added to the [Benefit Drug List](#) effective 01 December 2013:

Protocol Title	Protocol Code	Benefit Status
Therapy for Advanced Breast Cancer Using Everolimus and Exemestane	BRAVEVEX	Class II
Palliative Therapy for Metastatic Castration Resistant Prostate Cancer Using Enzalutamide	UGUPENZ	Restricted

REVISED PROGRAMS

The following program has been revised on the [Benefit Drug List](#) effective 01 December 2013:

Protocol Title	Protocol Code	Benefit Status
Therapy for Advanced Renal Cancer Using Everolimus	GUEVER	Class II (Previously Restricted)

SYSTEMIC THERAPY UPDATE EDITORIAL BOARD

EDITORIAL BOARD MEMBERSHIP

The Systemic Therapy Update Editorial Board would like to bid farewell to Jaya Venkatesh (prior Director of Business Affairs) and Lindsay Schwartz (prior Education Resource Nurse), and extend our sincere thanks for their many contributions to the Systemic Therapy Update. We wish them all the best in their new endeavours. The board would also like to welcome Ava Hatcher, Education Resource Nurse from Professional Practice Nursing, as the new nursing representative on the Board. Welcome, Ava.

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
BRAVEVEX	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Therapy for Advanced Breast Cancer Using Everolimus and Exemestane
GINPRRT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Out-of-Province Peptide Receptor Radionuclide Therapy for Advanced Neuroendocrine Tumors
UGUPENZ	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Palliative Therapy for Metastatic Castration Resistant Prostate Cancer Using Enzalutamide
HNNAVPE	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Treatment of Recurrent and/or Metastatic Nasopharyngeal Cancer with Platinum and Etoposide

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

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
BRAJTAM	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Treatment duration clarified</i>	Adjuvant Therapy for Breast Cancer Using Tamoxifen
BRAVEXE	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Eligibility clarified</i>	Palliative Therapy for Advanced Breast Cancer Using Exemestane
UGIFIRINOX	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Prophylactic atropine added</i>	Palliative Combination Chemotherapy for Metastatic Pancreatic Adenocarcinoma Using Irinotecan, Oxaliplatin, Fluorouracil and Folinic Acid (Leucovorin)
GIHIPEC	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Treatment and BSA calculation clarified</i>	Hyperthermic Intraperitoneal Chemotherapy (HIPEC) for Patients with Peritoneal Carcinomatosis from Limited Advanced Colorectal and Appendiceal Carcinomas Using Oxaliplatin and Fluorouracil (5-FU)
UGIPNEVER	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Minor typo corrected in Precautions section</i>	Palliative Treatment of Advanced Pancreatic Neuroendocrine Tumours using Everolimus
GUEVER	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Protocol Code and Eligibility revised</i>	Therapy for Advanced Renal Cancer Using Everolimus
UGUPABI	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Eligibility and Tests clarified</i>	Palliative Therapy for Metastatic Castration Resistant Prostate Cancer Using Abiraterone and prednisONE

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

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
UGUPCABA	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Eligibility clarified</i>	Palliative Therapy for Metastatic Castration Resistant Prostate Cancer Using Cabazitaxel and predniSONE
HNAVFUP	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Caution on cardiotoxicity updated</i>	Treatment of Advanced Squamous Cell Carcinoma of the Head and Neck Cancer Using Fluorouracil and Platinum
HNNAVFUP	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Caution on cardiotoxicity updated</i>	Treatment for Advanced Nasopharyngeal Cancer of the Head and Neck using Platinum and Fluorouracil
HNNAVPG	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Carboplatin option added; Protocol Title updated</i>	Treatment of Locoregionally Recurrent and/or Metastatic Nasopharyngeal Cancer with Platinum and Gemcitabine
HNOTTSH	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Eligibility updated</i>	Radioiodine Imaging in Patients with Thyroid Cancer using Thyrotropin Alpha
UMYMPT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Exclusions clarified</i>	Treatment of Multiple Myeloma Using Melphalan, Prednisone and Thalidomide

WEBSITE RESOURCES AND CONTACT INFORMATION

WEBSITE RESOURCES	www.bccancer.bc.ca
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

CONTACT INFORMATION	PHONE	FAX	EMAIL
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Provincial Systemic Therapy Program	604-877-6000 x 672247		mclin@bccancer.bc.ca
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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