



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 1 October 2015:

Genitourinary:

Enzalutamide for Chemotherapy Naïve Patients with Asymptomatic Metastatic Castration Resistant Prostate Cancer (mCRPC) (UGUPENZ) – Treatment with enzalutamide at the BC Cancer Agency was previously restricted to patients with symptomatic mCRPC after docetaxel chemotherapy. This has now been expanded to include chemotherapy naïve patients with asymptomatic or mildly symptomatic disease. In one placebo-controlled phase III trial involving 1717 patients, enzalutamide was associated with improved median overall survival (32.4 mo vs. 30.2 mo, HR 0.71 [95% CI 0.60-0.84]) and median radiographic progression free survival (median not reached vs. 3.9 mo, HR 0.19 [95% CI 0.15-0.23]).¹ The toxicity profile of enzalutamide was similar to that seen in previous trials with symptomatic patients.

Enzalutamide offers an alternative to the current standard treatment of abiraterone plus prednisone (UGUPABI). Since these two regimens have not been directly compared in a phase III trial, the choice of treatment would be mainly based on the patients' tolerability to the treatment regimens.

Effective October 1st, a BCCA Compassionate Access Program (CAP) approval will be required. Patients previously treated with enzalutamide for this indication prior to October 1st will fall into the following categories:

EDITOR'S CHOICE

- Patients enrolled in the XTANDI® Patient Assistance Program (XPAP) by Astellas Pharma Inc.:
 - Prior to August 1st – continue to be grandfathered by the XPAP
 - Between August 1st and 16th – will NOT be grandfathered by the XPAP, and will require a new BCCA CAP submission
- Patients previously granted BCCA CAP approval between August 17th and September 30th will NOT require a new CAP submission.

1. Beer TM, Armstrong AJ, Rathkopf DE, et al. Enzalutamide in metastatic prostate cancer before chemotherapy. NEJM 2014; 371(5): 424-33.

Gastrointestinal:

Lanreotide for the Treatment of Functional Carcinoid and Neuroendocrine Tumours of the Gastrointestinal Tract (UGILAN) – Intramuscular octreotide is the standard long-acting drug therapy for patients with functional carcinoid and neuroendocrine tumours of the GI tract (UGIOCTLAR). Subcutaneous lanreotide is another long-acting analog with similar efficacy in controlling symptoms and biochemical markers associated with growth hormone secretion.

DRUG UPDATE

NEW FDA LABELLING STANDARDS FOR PREGNANCY AND LACTATION

The US Food and Drug Administration (FDA) has set new labelling standards for medication use during pregnancy and lactation. The new standards will cease the use of the pregnancy letter category system (A, B, C, D, and X), which was thought to provide an oversimplified view of the product risk and often misinterpreted as a grading system. Rather, three new subsections will be added to all new drug products –“Pregnancy”, “Lactation”, and “Females and Males of Reproductive Potential”. These subsections will include information on the potential risks along with the supporting data.

Effective 30 June 2015, all newly approved drugs (prescription drugs and biologic products) were mandated to follow the new labelling standards. Labelling revisions for previously approved drugs will be phased in gradually over the next 3 to 5 years.

As the FDA changes are phased in, the BCCA Cancer Drug Manual Monographs will be updated to delete the pregnancy letter categories from the Special Precautions (Pregnancy) section, and will include added information on the associated risks as necessary.

Reference:

1. FDA News Release [Internet]. FDA issues final rule on changes to pregnancy and lactation labelling information for prescription drug and biological products; 2014 Dec 3. Available from: www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm425317.htm.
2. US Department of Health and Human Services, Food and Drug Administration. Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products – Content and Format. Guidance for Industry (Small Entity Compliance Guide). June 2015.

CANCER DRUG MANUAL

REVISED MONOGRAPHS AND PATIENT HANDOUTS

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

Ramucirumab Monograph and **Chemotherapy Preparation & Stability Chart (CPSC):**

- Notice of Compliance has been granted
- Updated *Uses, Parenteral Administration* table, and *Supply and Storage* sections

Updated Supplier in **Supply and Storage** section:

- Dabrafenib Monograph
- Lapatinib Monograph
- Pazopanib Monograph

BENEFIT DRUG LIST

NEW PROGRAMS

The following program has been added to the [Benefit Drug List](#) effective 1 October 2015:

Protocol Title	Protocol Code	Benefit Status
Symptomatic Management of Functional Carcinoid and Neuroendocrine Tumours of the GI Tract using Lanreotide	UGILAN	Restricted

CONTINUING PROFESSIONAL DEVELOPMENT

BCCA FAMILY PRACTICE ONCOLOGY NETWORK CME EVENTS

The BCCA Family Practice Oncology Network (FPON) is hosting 2 CME Events in November 2015.

Date: November 20 – Oncology Imaging for Primary Care
November 21 – FPON CME Day

Location: BCCA Cancer Research Centre, 675 W 10th Avenue, Vancouver

Registration: Online registration ends November 19th
Onsite registration available for an additional \$25

The event agenda and registration details can be found on the BCCA Continuing Medical Education website at: www.bccancer.bc.ca/health-professionals/networks/family-practice-oncology-network/continuing-medical-education.

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 BCCA Compassionate Access Program approval are prefixed with the letter “U”.

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

CODE	Protocol	PPPO	Patient Handout	Protocol Title
UGILAN	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Symptomatic Management of Functional Carcinoid and Neuroendocrine Tumours of the GI Tract Using Lanreotide

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

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
GOCXAJCAT	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Space for doctor's signature added to page 1</i>	Primary Adjuvant Treatment of Adenocarcinoma/Adenosquamous Cancer of the Cervix with CARBOplatin and PACLitaxel Prior to Irradiation with or without CISplatin
UGUPENZ	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Eligibility criteria expanded</i>	Palliative Therapy for Metastatic Castration Resistant Prostate Cancer Using Enzalutamide
LUSCPI	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Threshold of platelet count for continuation of treatment revised; TALLman lettering implemented</i>	Second-Line Treatment of Extensive Stage Small Cell Lung Cancer (SCLC) with Irinotecan With or Without Platinum
LYCDA	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Tests clarified</i>	Treatment of Hairy Cell Leukemia with Cladribine
UMYBORPRE	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Cyclophosphamide dose reduction clarified</i>	Treatment of Multiple Myeloma Using Bortezomib, Dexamethasone With or Without Cyclophosphamide as Induction Pre-Stem Cell Transplant
UMYBORREL	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Cyclophosphamide dose reduction clarified</i>	Treatment of Relapsed Multiple Myeloma using Bortezomib, Dexamethasone With or Without Cyclophosphamide
MYMP	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Endpoint to treatment duration added</i>	Treatment of Multiple Myeloma Using Melphalan and Prednisone
UMYMPBOR	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Cyclophosphamide dose reduction clarified</i>	Treatment of Multiple Myeloma using Melphalan, predniSONE and Weekly Bortezomib With the Option of Substituting Cyclophosphamide for Melphalan
UMYPOMDEX	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Serum creatinine added to the Return Laboratory section for cycles 1 and 2</i>	Therapy of Multiple Myeloma Using Pomalidomide with Dexamethasone

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

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
SAAJGI	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Eligibility, blood work for Dose Modifications and Drug Interactions revised</i>	Adjuvant Treatment of C-Kit Positive High Risk Gastrointestinal Stromal Cell Tumours Using Imatinib
SAAVGEMD	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Docetaxel starting dose reduced</i>	Therapy for Soft Tissue Sarcomas using Gemcitabine and DOCetaxel

ERRATUM**CORRECTION TO SEPTEMBER 2015 SYSTEMIC THERAPY UPDATE**

In the table for NEW Protocols, PPPOs and Patient Handouts, the protocol title for LULACATRT should read as follows:

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

CODE	Protocol	PPPO	Patient Handout	Protocol Title
LULACATRT	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Treatment of Locally Advanced Non-Small Cell Lung Cancer using CARBO platin and PAC Litaxel with Radiation Therapy

WEBSITE RESOURCES AND CONTACT INFORMATION

WEBSITE RESOURCES	www.bccancer.bc.ca
Systemic Therapy Update	www.bccancer.bc.ca/health-professionals/professional-resources/systemic-therapy/systemic-therapy-update
Reimbursement & Forms: Benefit Drug List, Class II, Compassionate Access Program	www.bccancer.bc.ca/health-professionals/professional-resources/systemic-therapy
Cancer Drug Manual	www.bccancer.bc.ca/health-professionals/professional-resources/cancer-drug-manual
Cancer Management Guidelines	www.bccancer.bc.ca/health-professionals/professional-resources/cancer-management-guidelines
Cancer Chemotherapy Protocols, Pre-printed Orders, Protocol Patient Handouts	www.bccancer.bc.ca/health-professionals/professional-resources/chemotherapy-protocols
Systemic Therapy Program Policies	www.bccancer.bc.ca/health-professionals/professional-resources/systemic-therapy
CON Pharmacy Educators	www.bccancer.bc.ca/health-professionals/professional-resources/pharmacy

CONTACT INFORMATION	PHONE	FAX	EMAIL
Systemic Therapy Update Editor			bulletin@bccancer.bc.ca
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	604-877-6000 x 672247		mclin@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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