Systemic Therapy Update

BC Cancer Agency
CARE + RESEARCH
An agency of the Provincial Health Services Authority

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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 new programs effective September 2012:

Breast:

DOCEtaxel, Cyclophosphamide with Concurrent Trastuzumab in Adjuvant Treatment of HER2-Positive Breast Cancer (BRAJTDC) – DOCEtaxel and cyclophosphamide (BRAJDC), followed by sequential trastuzumab (BRAJTR), has been a treatment option for patients with HER2-positive breast cancer at the BCCA for some years. A recent phase II trial of 486 patients demonstrated that concurrent use of all three agents yielded a disease-free survival of 96.3% and an overall survival of 98.5% at 3 years. Cardiac dysfunction (all grades) occurred in 6% of patients; however grade 3 toxicity occurred in only 0.4%. Sixteen of 486 patients (3%) discontinued trastuzumab for cardiac toxicity. ***[Jones S et al. SABCS 2011, Abstract PD07-03]*** This toxicity profile is similar to those described for other concurrent chemotherapy and trastuzumab regimens approved by the BCCA. The concurrent use of DOCEtaxel, cyclophosphamide (4 cycles) and trastuzumab (17 cycles) as described in the new protocol BRAJTDC has been approved for use without need for Compassionate Access Program (CAP) approval based on these data. The new protocol also

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reduces the total number of treatment cycles by 4 (from 21 to 17), a favourable change for the patient and the institution.

Gastrointestinal:

Adjuvant CISplatin and Capecitabine for Gastric Cancer Patients with D2 Resection (Node Negative) or Patients Ineligible for Adjuvant Chemoradiation (UGIGAJCC) – This chemotherapy protocol is indicated for a select group of patients who have been treated with D2 resection – the most widely accepted gastric surgical procedure in Asia and Europe. In the ARTIST trial involving 458 patients with gastric adenocarcinoma, grades 3 and 4 neutropenia occurred in 35% and 5.7% of patients, respectively. *[Lee J et al. J Clin Onc 2012;30:268-273]* The most common grades 3 and 4 non-hematologic adverse events were vomiting (3.5%), stomatitis (1.3%), hand-foot syndrome (2.2%) and diarrhea (2.2%). This protocol is a feasible and tolerable treatment option for this select patient population.

COMMUNITIES ONCOLOGY NETWORK

BC CANCER AGENCY INFORMATION SYSTEM (CAIS) ACCESS FOR CON STAFF

Communities Oncology Network (CON) staff responsible for managing oncology patients can request remote access to the BCCA CAIS. The goal is to facilitate the transfer of care for cancer patients, and to ensure CON staff in the Health Authorities has access to pertinent BCCA patient information. To request remote access to CAIS, please email the respective contacts in your Health Authority listed below. You will be sent the appropriate request form and the PHSA policy regarding network access, computing, information management and data confidentiality and security.

BCCA: citrix_bcca@bccancer.bc.ca
FHA: citrix_bcca@bccancer.bc.ca
IHA: ksmith2@bccancer.bc.ca (BCCA SAHCSI)
NHA: citrix_bcca@bccancer.bc.ca
VCH: citrix_bcca@bccancer.bc.ca
VIHA: colleen.butcher@viha.ca (Director Medicine)

Please note that CON staff must use a Health Authority email address rather than a personal email address to request remote CAIS access.

DRUG UPDATE

ALEMTUZUMAB: CHANGE IN DRUG ACCESS

Effective 04 September 2012, alemtuzumab will no longer be commercially available but can be accessed free of charge through the Clinigen MabCampath Distribution Program (CDP) until further notice – Patients treated under the BCCA ULYALEM chemotherapy protocol *[Treatment of Fludarabine-Refractory B-Chronic Lymphocytic Leukemia (B-CLL) and T-Prolymphocytic Leukemia (T-PLL) with Alemtuzumab]* are eligible to apply for alemtuzumab access through the CDP. The CDP approves

alemtuzumab access in patients requiring therapy for Chronic Lymphocytic Leukemia (CLL) as per approved Health Canada indications, and provides conditional approval for T-Cell Prolymphocytic Leukemia (T-PLL) upon a routine medical review. The treating institution is required to establish an account with Clinigen to initiate the drug access process. Physicians must also submit a patient-specific application to the CDP for all current and new patients at least 1 week prior to the scheduled treatment. Only a limited supply will be shipped per patient, after which the physician must submit a request for continuation of treatment. For further information and to establish an account with the CDP, please contact the MabCampath Distribution Program Customer Service Team at 1-866-596-8940. Please note that physicians must continue to submit the BCCA CAP requests.

DALTEPARIN AND ENOXAPARIN: REVISED SPECIAL AUTHORITY ACCESS

Effective immediately, BC PharmaCare has revised the Special Authority criteria for the drug coverage of two low-molecular weight heparins, Dalteparin and Enoxaparin, to include two new indications:

1) *PROPHYLAXIS* of venous thromboembolism (VTE) following abdominal or pelvic surgery for the management of a malignant tumour (approval period up to 10 days)

2) *PROPHYLAXIS* of VTE following abdominal or pelvic surgery for the management of a malignant tumour *AND WHO ARE AT HIGH RISK* as defined by the following criteria**:** (approval period up to 28 days)
   - Previous history of VTE, and/or
   - Anaesthesia lasting longer than 2 hours, and/or
   - Bed rest lasting 4 days or longer following surgery

These indications are approved in addition to the pre-existing cancer-related indication:

- *TREATMENT* of VTE in patients, associated with cancer, who have failed, or who are unable to tolerate, oral therapy with warfarin (approval period up to 6 months for *DALTEPARIN ONLY*)

BC PharmaCare has updated its Special Authority Request Form to include the new indications. BCCA Pharmacy will also be updating its internal documents to reflect this recent change.

DRUG SHORTAGE UPDATE: MEGESTROL

AA Pharma is facing a **temporary supply shortage of Megestrol 40 mg and 160 mg tablets**. Both tablet strengths are expected to be available in October 2012. Megestrol is indicated for the treatment of advanced endometrial and breast cancer. Prescribers and pharmacies will continue to collaborate to allocate the stock for patients already booked for treatment. Please note that Bristol-Myers Squibb Canada carries megestrol 40 mg/mL oral suspension that is currently available.

Cancer Drug Manual

Revised Monographs and Patient Handouts

Topotecan:

- The Hospira brand of topotecan 4 mg single-use vials has been added to the Chemotherapy Preparation and Stability Chart.

Farewell to Editorial Board Member

The **Cancer Drug Manual Team** and **Editorial Board** would like to bid farewell to exiting Editorial Board member, **Dr. Greg Dueck**, as he steps down from the Board in September 2012. The team would like to extend its sincere thanks to Dr. Dueck for his many contributions, and to wish him all the best in his new role as Physician Professional Practice Leader at the BCCA Sindi Ahluwalia Hawkins Centre for the Southern Interior (SAHCSI). Dr. Susan Ellard, medical oncologist at SAHCSI, will be joining the Editorial Board during Dr. Dueck's absence. Welcome Dr. Ellard!

Benefit Drug List

New Programs

The following programs have been added to the Benefit Drug List effective September 2012:

- **CISplatin** and **Capecitabine** (restricted) for adjuvant treatment of gastric cancer patients with D2 resection (node negative) or ineligible for adjuvant chemoradiation (UGIGAJCC)
- **DOCEtaxel, Cyclophosphamide** with **Concurrent Trastuzumab** (class II) for adjuvant treatment of HER2-positive breast cancer (BRAJTDC)

Revised Programs

The following program has been revised in the Benefit Drug List effective 01 September 2012:

- **DOCEtaxel, CARBOplatin** with **Trastuzumab** (class II) for adjuvant treatment of HER2-positive breast cancer (BRAJDCARBT) (formerly known as UBRAJDCT)

Deleted Programs

The following program has been removed from the Benefit Drug List effective 01 September 2012 to reflect current practice:

- **DOCEtaxel, CISplatin** and **Infusional Fluorouracil** (class II) for the palliative treatment of metastatic or locally advanced gastric, esophagogastric junction, or esophageal adenocarcinoma (GIGDCF)

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
BRAJTDC	☑	☑	☐	Adjuvant Therapy for Breast Cancer Using Trastuzumab, DOCEtaxel and Cyclophosphamide
UGIGAJCC	☑	☑	☐	Adjuvant Chemotherapy for Gastric Cancer Patients with D2 Resection (Node Negative) or Ineligible for Adjuvant Chemoradiation Using CISplatin and Capecitabine

REVISED Protocols, PPPOs and Patient Handouts (AFFECTED DOCUMENTS ARE CHECKED):

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
BRAJACTT	☑	☐	☐	*Updated Precautions section, implemented TALLman lettering*	Adjuvant Therapy for Breast Cancer using DOXOrubicin and Cyclophosphamide followed by PACLitaxel and Trastuzumab
BRAJDC	☑	☐	☐	*Corrected dosing recommendations for Febrile Neutropenia, implemented TALLman lettering*	Adjuvant Therapy for Breast Cancer Using DOCEtaxel and Cyclophosphamide
BRAJDCARBT	☑	☑	☑	*Revised Protocol Code – formerly known as UBRAJDCT, corrected dosing recommendations for Febrile Neutropenia, updated Precautions section*	Adjuvant Therapy for Breast Cancer Using DOCEtaxel, CARBOplatin and Trastuzumab
BRAJFECDT	☑	☐	☐	*Updated Precautions section, implemented TALLman lettering*	Adjuvant Therapy for Breast Cancer using Fluorouracil, Epirubicin and Cyclophosphamide followed by DOCEtaxel and Trastuzumab
BRAJTR	☑	☑	☐	*Updated Eligibility, clarified Treatment section, updated Precautions section; PPO – added requirement to indicate number of previous trastuzumab doses given in trastuzumab-containing chemotherapy regimen*	Adjuvant Therapy for Breast Cancer using Trastuzumab following the Completion of Chemotherapy (Sequential)
BRAVTPCARB	☑	☑	☑	*Revised Protocol Code – formerly known as BRAVTPC, implemented TALLman lettering*	Palliative Therapy for Metastatic Breast Cancer using Trastuzumab, PACLitaxel and CARBOplatin as First-Line Treatment for Advanced Breast Cancer

REVISED PROTOCOLS, PPPOS AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED):					
CODE	**Protocol**	**PPPO**	**Patient Handout**	**Changes**	**Protocol Title**
BRAVTR	☑	☑	☑	*Revised Eligibility, clarified Treatment section and implemented TALLman lettering; PPO – added requirement to indicate number of previous trastuzumab doses given in trastuzumab-containing chemotherapy regimen*	Palliative Therapy for Metastatic Breast Cancer Using Trastuzumab
UGIYTT	☑	☐	☐	*Corrected minor typo*	Yttrium-90 for Transarterial Radioembolisation (TARE)
ULYALEM	☑	☑	☐	*Updated Eligibility to include information on alemtuzumab access*	Treatment of Fludarabine-Refractory B-Chronic Lymphocytic Leukemia (B-CLL) and T-Prolymphocytic Leukemia (T-PLL) with Alemtuzumab
ULYRICE	☑	☑	☐	*Updated Contact Physician, clarified etoposide dose, added need to use non-PVC equipment, and implemented TALLman lettering*	Treatment of Advanced Stage Large B-Cell Non-Hodgkin's Lymphoma with Ifosfamide, CARBOplatin, Etoposide and RiTUXimab

DELETED Protocols, PPPOs and Patient Handouts (AFFECTED DOCUMENTS ARE CHECKED):				
CODE	**Protocol**	**PPPO**	**Patient Handout**	**Protocol Title**
GIGDCF	☑	☑	☑	Palliative Treatment of Metastatic or Locally Advanced Gastric, Esophagogastric Junction, or Esophageal Adenocarcinoma Using DOCEtaxel, CISplatin and Infusional Fluorouracil

Website Resources and Contact Information

Website Resources	www.bccancer.bc.ca
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
Systemic Therapy Update	www.bccancer.bc.ca/HPI/ChemotherapyProtocols/stupdate
CON Pharmacy Educators	http://www.bccancer.bc.ca/HPI/Pharmacy/ContactUs.htm

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Communities Oncology Network (CON)	250.519.5501		jdenduyf@bccancer.bc.ca
Oncology Drug Information	604.877.6275		druginfo@bccancer.bc.ca
Education Resource Nurse	604.877.6000 x 2638		nursinged@bccancer.bc.ca
Library/Cancer Information	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 2623		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-Sindi Ahluwalia Hawkins Centre for the Southern Interior	250.712.3900 Toll Free 888.563.7773		
BCCA-Fraser Valley Centre	604.930.2098 Toll Free 800.523.2885		
BCCA-Vancouver Centre	604.877.6000 Toll Free 800.663.3333		
BCCA-Vancouver Island Centre	250.519.5500 Toll Free 800.670.3322		

Editorial Review Board