Systemic Therapy Update

BC Cancer Agency
CARE + RESEARCH
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For Health Professionals Who Care For Cancer Patients

Inside This Issue:

EDITOR'S CHOICE

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

Breast:

The Provincial Systemic Therapy Program has approved 12 weeks of **weekly PACLitaxel** following 4 cycles of DOXOrubicin-cyclophosphamide in the **adjuvant treatment of high-risk breast cancer (UBRAJACTW)**. This is now a standardized treatment option in women with either node-positive or high-risk node-negative, HER2-negative breast cancer. A phase III, 4-arm clinical trial involving 4950 patients investigated 3-weekly PACLitaxel or DOCEtaxel and weekly PACLitaxel or DOCEtaxel. Compared to 3-weekly PACLitaxel, weekly PACLitaxel was associated with a superior 5-yr overall survival (OS) (89.7% vs. 86.5%, HR 1.32) and 5-yr disease free survival (DFS) (81.5% vs. 76.9%, HR 1.27). [Sparano *et al. NEJM* 2008;358:1663-71] Patients randomized to weekly PACLitaxel generally experienced lower rates of toxicities compared with 3-weekly PACLitaxel and 3-weekly DOCEtaxel, with the exception of a higher incidence of grades 2 to 4 neuropathy.

Unlike 2-weekly dose-dense PACLitaxel (BRAJACTG), weekly PACLitaxel does not require G-CSF support. For the time being, this regimen will require Compassionate Access Program submission although requests will be automatically approved for the described population.

VACCINATION AGAINST "SHINGLES" IN LYMPHOID CANCER PATIENTS

The **Lymphoma/Myeloma Tumour Group** is recommending **varicella zoster virus vaccination (ZOSTAVAX®)** in all patients with lymphoid cancer for the prevention of herpes zoster infections, commonly known as *shingles*. The tumour group has developed a Patient Information Handout and updated the information on the Cancer Management Guidelines website.

BCCA Recommendations: A single dose may be given either before or after anti-lymphoid cancer treatment.

Pre-Treatment
- At time of diagnosis if it can be given at least 2 weeks before initiation of anti-lymphoid cancer treatment

OR

Post-Treatment
- If lymphoid cancer has been in remission (completely absent) for more than 6 months

OR

- If lymphoid cancer is not in remission (present but not in need of treatment), but patient has been off treatment (including corticosteroids and any other immunocompromising medications), has been clinically well, and has no evidence of opportunistic or unusual infections for more than 6 months

Background

Herpes zoster presents with a band-like rash that is often accompanied by neuropathic pain (postherpetic neuralgia). The pain can persist even after the rash has completely resolved. It is caused by a reactivation of the varicella zoster virus (VZV) which causes chicken pox, the primary infection that generally occurs in childhood. The virus can remain dormant within the sensory ganglia for many years and reactivate decades later.

Between 10% and 50% of patients with lymphoid cancer develop shingles with variable risk of postherpetic neuralgia and rare fatality. Although recurrent infections are uncommon in healthy individuals, immuncompromised hosts are at higher risk for recurrent events. In adults over the age of 60, ZOSTAVAX® has been shown to reduce the risk of herpes zoster by 50%. [Oxman *et al. NEJM* 2005;352:2271-84]

Lymphoid cancer was considered a contraindication when ZOSTAVAX® was first marketed due to concerns of acute infections with the administration of live viruses. It is now recognized that lymphoid cancer patients are at significantly higher risk of herpes zoster, and that highly immunocompromised patients (i.e. post-BMT transplantation) can safely tolerate ZOSTAVAX® without adverse events. The US Centre for Disease Control (CDC) has subsequently modified their recommendations such that ZOSTAVAX® can be safely administered to patients whose lymphoid cancer has been in remission for more than 3 months. Further information on these recommendations can be found on the CDC Morbidity and Mortality Weekly Report (06 Jun 2008, Vol 57, RR-5).

Availability

ZOSTAVAX® can be accessed through the family physician. It is not a benefit drug of the BC Cancer Agency or the BC PharmaCare Program, but is covered by many extended health care plans with an estimated cost of $150 to $175.

Please note that while there are 2 varicella virus vaccines on the market (ZOSTAVAX® and VARIVAX®), only ZOSTAVAX® is indicated for the prevention of herpes zoster infections.

Submitted by: Dr. Joseph Connors (MD)
Clinical Professor & Director
BCCA Centre for Lymphoid Cancer

Drug Update

Sandoz Canada Drug Shortages

Sandoz Canada Inc. is facing ongoing **drug production challenges** that have resulted in significant drug supply shortages across Canada. These shortages are expected to continue for an extended period of time. In a concerted effort to maintain drug access to patients across British Columbia, the BC Cancer Agency, BC Health Authorities, the Health Shared Services BC and the Ministry of Health continue to collaborate to share information on drug reallocation, to address potential shortages, and to discuss strategies to minimize the impact on patient care. Pharmacy leadership across BC will continue to provide status updates on the Sandoz drug supplies and allocation to their individual health organizations. For health authorities within the Lower Mainland, drug shortage announcements are posted on the Fraser Health Pulse Drug Shortage Update website or your health organization's intranet home page (access by selecting the Sandoz button).

Communities Oncology Network

New Initiative: Protocol Code Entries Into OSCAR

The BC Cancer Agency's Provincial Systemic Therapy Program is collaborating with the Communities Oncology Network (CON) hospitals in BC to implement BCCA treatment protocol code entries by CON hospitals into the Online System for Cancer drugs Adjudication and Reimbursement (OSCAR).

The goal is to obtain BCCA protocol codes on the prescription or physician order for all systemic treatments. Use of the BCCA preprinted orders will facilitate the identification of the protocol code. Ideally, each of the claims submitted for reimbursement on OSCAR will be accompanied by a BCCA protocol code. This initiative will be implemented via a phased-in approach commencing 01 April 2012.

Rationale for Submission of Protocol Codes
The Provincial Systemic Therapy Program develops, implements and evaluates standards of systemic care for patients within the BCCA and CON sites based on best scientific evidence derived from clinical trials in cancer patients. Therapy is standardized through the creation of chemotherapy protocols, which are regularly reviewed and updated to reflect new knowledge and practice. There are more than 350 BCCA chemotherapy protocols available to patients for a broad range of malignancies.

The current initiative allows for the capture of essential data used to track and predict provincial utilization of drugs. Each protocol code identifies the tumour site, treatment intent and the drugs used. Therefore, access to this information is crucial to the accuracy of the drug budgeting process. It also enables the BCCA to perform sophisticated projections in the future use of new and costly agents, and track how these predictions have performed in practice.

Project Plan
There are several internal and external processes, and software compatibility issues which need to be addressed over the next 6 to 12 months to maximize the accuracy of protocol code submissions. Hence, this initiative will take a phased-in approach.

As an initial information gathering step, a survey was conducted and its results were used to formulate a plan for implementation. Key components of the plan include software compatibility, communication to

Communities Oncology Network

key stakeholders, development of BCCA protocol codes as necessary, education, on-going support and funding. Development of a FAQ sheet is underway, and will be circulated shortly. This document is intended to guide the selection of correct protocol codes.

Contact
The BCCA is committed to assisting staff in the CON hospitals to help provide accurate protocol codes. For questions or comments related to the submission of protocol codes, please contact the BCCA at 1-888-355-0355 or by email at oscar@bccancer.bc.ca.

Continuing Education

CAMEO: New Education Program

The Complementary Medicine Education and Outcomes (CAMEO) Program, a research program jointly supported by the UBC School of Nursing and the BC Cancer Agency, is pleased to announce the launch of an online, self-directed education program – "Supporting Safe and Informed CAM & Cancer Decisions". This program aims to help health care professionals support cancer patients in making evidenced-informed decisions around the use of complementary and alternative medicine (CAM). More information about the program can be found on the CAMEO website.

Upcoming Conferences

Realities of Northern Oncology Conference (RONOC):

Date: May 4-5, 2012
Location: Prince George Civic Centre, Prince George, BC
Registration Deadline: N/A
Website: http://www.ronoc.ca

With the new BCCA Centre for the North soon to open, RONOC is an opportunity to unite all cancer care providers within the North. Topics have been selected based on a needs assessment completed in 2011, with the focus on the Communities Oncology Network. Objectives for this conference include:

- To become familiar with surveillance and survivorship concerns and solutions for the North
- To expand on knowledge of radiation therapy treatment
- To improve on patient care in the palliative setting
- To review symptom management control for the paediatric oncology patient
- To enhance management of oncologic emergencies
- To explore alternative and complementary care options

CANCER DRUG MANUAL

NEW MONOGRAPHS AND PATIENT HANDOUTS

Ofatumumab Interim Monograph, Chemotherapy Preparation and Stability Chart, and **Hazardous Drug Evaluation** have been completed. Ofatumumab has also been added to the **BCCA NIOSH HD List Addendum**. Ofatumumab is a human immunoglobulin monoclonal antibody indicated primarily for chronic lymphocytic leukemia. It is associated with infusion-related reactions that may occur on initial and subsequent infusions, and require premedications with analgesics, antihistamines and corticosteroids.

Ofatumumab requires access through the Health Canada Special Access Programme (SAP) and is not a benefit drug of the BCCA.

BENEFIT DRUG LIST

NEW PROGRAMS

The following program has been added to the Benefit Drug List effective 01 April 2012:

- **Weekly PACLitaxel** (restricted funding) with DOXOrubicin and Cyclophosphamide for the adjuvant treatment of node-positive or high-risk node-negative breast cancer (UBRAJACTW)

REVISED PROGRAMS

The following programs have been revised in the Benefit Drug List effective 01 April 2012:

- **Interferon alfa** – removed the following indications to reflect current practice: (1) lymphoproliferative disease, (2) myeloproliferative disease, (3) post-bone marrow transplant and (4) multiple myeloma
- **Megestrol** – removed the following indication to reflect current practice: prostate cancer
- **Tamoxifen** – removed the following indication to reflect current practice: pancreatic carcinoma in postmenopausal women

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
UBRAJACTW	☐	☐	☑	Adjuvant Therapy for Early Breast Cancer using DOXOrubicin and Cyclophosphamide followed by Weekly PACLitaxel
GUAVD	☑	☑	☐	Palliative Therapy for Advanced Adrenal Cortical Cancer Using DOXOrubicin
GUMITO	☑	☑	☑	Treatment of Adrenal Cortical Cancer with Mitotane
HNOTAVD	☑	☑	☐	Palliative Therapy for Advanced Thyroid Cancers Using DOXOrubicin

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

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
BRAVCMPO	☐	☑	☐	*Rounding dose deleted from initial dosing*	Palliative Therapy for Metastatic Breast Cancer Using Metronomic Low-Dose Oral Cyclophosphamide and Methotrexate
BRLAACD	☑	☐	☐	*Added information on febrile neutropenia to Precautions section*	Treatment of Locally Advanced Breast Cancer Using DOXOrubicin and Cyclophosphamide Followed by DOCEtaxel (TAXOTERE®)
BRLAACDT	☑	☐	☐	*Added information on febrile neutropenia to Precautions section*	Treatment of Locally Advanced Breast Cancer Using DOXOrubicin and Cyclophosphamide Followed by DOCEtaxel (TAXOTERE®) and Trastuzumab
UCNBEV	☐	☑	☐	*Infusion time for first cycle clarified*	Palliative Therapy for Recurrent Malignant Gliomas Using Bevacizumab.
GOOVCAG	☐	☑	☐	*Revised labs section under Return Appointment Orders*	Treatment of Advanced Ovarian Cancer in Patients Who Have Progressed or Recurred Following First-Line Platinum-Based Treatment Using CARBOplatin and Gemcitabine

REVISED PROTOCOLS, PPPOS AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED):					
CODE	**Protocol**	**PPPO**	**Patient Handout**	**Changes**	**Protocol Title**
UHNLACETRT	☑	☐	☐	*Updated References*	Combined Cetuximab and Radiation Treatment for Locally Advanced Squamous Cell Carcinoma of the Head and Neck
ULKCMLD	☑	☐	☐	*Updated information on pulmonary arterial hypertension under Side Effects*	Treatment of Chronic Myeloid Leukemia and Ph+ Acute Lymphoblastic Leukemia Using Dasatinib (SPRYCEL®)
LUAVPEM	☐	☐	☑	*Clarified dexamethasone dosing information*	Second-Line Treatment of Advanced Non-Small Cell Lung Cancer (NSCLC) with Pemetrexed
ULUAVPMTN	☐	☐	☑	*Clarified dexamethasone dosing information*	Maintenance Therapy of Advanced Non-Small Cell Lung Cancer (NSCLC) with Pemetrexed
ULUAVPP	☐	☐	☑	*Clarified dexamethasone dosing information*	First-Line Treatment of Advanced Non-Small Cell Lung Cancer with Platinum and Pemetrexed
ULUAVPP (CARBOplatin Option)	☐	☐	☑	*Clarified dexamethasone dosing information*	First-Line Treatment of Advanced Non-Small Cell Lung Cancer with Platinum and Pemetrexed
LUMMPP	☐	☐	☑	*Clarified dexamethasone dosing information*	Treatment of Malignant Mesothelioma with Platinum and Pemetrexed
LUMMPP (CARBOplatin Option)	☐	☐	☑	*Clarified dexamethasone dosing information*	Treatment of Malignant Mesothelioma with Platinum and Pemetrexed

DELETED Protocols, PPPOs and Patient Handouts (AFFECTED DOCUMENTS ARE CHECKED):				
CODE	**Protocol**	**PPPO**	**Patient Handout**	**Protocol Title**
ENAVD	☑	☑	☐	Palliative Therapy for Advanced Endocrine Cancers Using DOXOrubicin
ENMITO	☑	☑	☑	Treatment of Adrenal Cortical Cancer (Using Mitotane)

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

Contact Information	Phone	Fax	Email
Systemic Therapy Update Editor	604.877.6000 x 3028		sman3@bccancer.bc.ca
Provincial Systemic Therapy Program	604.877.707.5973		ldasilva2@bccancer.bc.ca
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		

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