Systemic Therapy Update



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For Health Professionals Who Care For Cancer Patients

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EDITOR'S CHOICE

New Program

The Provincial Systemic Therapy Program has approved the following treatment effective 01 June 2012:

Abiraterone with Prednisone for Symptomatic Patients with Metastatic Castration-Resistant Prostate Cancer (mCRPC) who are Ineligible for DOCEtaxel Treatment (UGUPABI) — Abiraterone with prednisone was previously approved for patients with mCRPC only after failure of DOCEtaxel. This was based on a randomized controlled trial that demonstrated overall survival benefit of 3.9 months at a median follow of 13 months. [de Bono et al. NEJM 2011;264:1995-2005] Recognizing that there are a number of patients who are not eligible for DOCEtaxel treatment with symptomatic, progressive disease, and that there is no alternative treatment available at this time, the BCCA Genitourinary Tumour Group has approved abiraterone for this patient population. A randomized, phase III trial is currently underway to evaluate abiraterone with prednisone in asymptomatic or mildly symptomatic patients as first-line mCRPC treatment. Results of this trial will be presented at the 2012 American Society of Clinical Oncology (ASCO) Meeting.

PROVINCIAL SYSTEMIC THERAPY PROGRAM POLICIES

REVISED POLICY III-20 - PREVENTION AND MANAGEMENT OF EXTRAVASATION OF CHEMOTHERAPY

Sodium thiosulfate 25% injection, an agent used to treat the extravasation of mechlorethamine (nitrogen mustard), is **no longer needed as part of the extravasation tray** as intravenous (IV) mechlorethamine is not commercially available in Canada. Should a centre carry IV mechlorethamine, they must carry sodium thiosulfate 25% injection as part of the extravasation tray. Please see the revised <u>Policy III-20</u> and the <u>May 2012</u> issue of the Systemic Therapy Update for further details.

NURSING UPDATE

REVISED NURSING PRACTICE REFERENCE (C-252) – ADMINISTRATION OF CHEMOTHERAPEUTIC AGENTS

In April 2012, BC Cancer Agency Nursing revised the <u>Nursing Practice Reference C-252</u>, "Administration of Chemotherapeutic Agents". These revisions were made in response to current best evidence surrounding chemotherapy administration and practice related changes (as per cited references below).

Additions to C-252 include:

- 1. Use of HOSPIRA SYMBIQ® infusion device for administering chemotherapy, with the exception of peripheral administration of vesicants or those given by elastomeric infusors (Directive 17)¹
- 2. Assessment of patency of a venous access device (peripheral or central) prior to administering chemotherapy by checking for blood return, and ensuring IV is free-flowing to gravity (Directive 19)²
- 3. Nursing actions to prevent and manage extravasation (Directives 24 & 25)^{2,3}
- 4. Procedure for sidearm administration via central venous access device ("Methods of Administration" section, p. 9) added in response to the standardization of central line administration of DOXOrubicin and epirubicin at the BCCA⁴

BCCA Pharmacies will dispense DOXOrubicin and epirubicin in syringes for administration by IV sidearm for both peripheral and central routes. For more information on the impetus for the standardization of this practice, please see the <u>March 2012</u> issue of the Systemic Therapy Update.

Submitted by: Michelle Moore RN BSN CON(C) Lindsay Schwartz RN MScA

Clinical Resource Nurse, ACCU Education Resource Nurse, Prov. Prof. Practice Nursing

Vancouver Centre, BCCA Vancouver Centre, BCCA

References:

- 1. BCCA Nursing Practice Reference Manual\I-490 IV Therapy Use of Hospira Symbig with DERS.doc
- 2. Infusion Nurses Society. 2011. Policies and Procedures for Infusing Nursing. 4th ed.
- 3. BC Cancer Agency. <u>Provincial Systemic Therapy Program Policy III-20: Prevention and Management of Extravasation of Chemotherapy</u>. Revised Feb 2012.
- 4. BC Cancer Agency. Systemic Therapy Update. March 2012.

DRUG UPDATE

ACCESS TO INTERFERON ALFA FOR NON-BENEFIT INDICATIONS

As per the April 2012 issue of the Systemic Therapy Update, interferon alfa is no longer a BCCA benefit drug for the following indications: (1) lymphoproliferative disease, (2) myeloproliferative disease, (3) postbone marrow transplant, and (4) multiple myeloma. Patients who initiated interferon alfa for one of the above indications **prior to 01 April 2012** may continue to receive refills for this drug <u>without</u> the need to apply for Compassionate Access Program approval if continuation of treatment is deemed beneficial by the prescribing physician.

UNAPPROVED INDICATIONS FOR LHRH AGONISTS IN BREAST CANCER PATIENTS

Luteinizing hormone-releasing hormone (LHRH) agonists are currently approved in combination with tamoxifen in the adjuvant setting in lieu of chemotherapy (BRAJLHRHT), as well as in the palliative setting (BRAVLHRHT) for breast cancer. All other uses of LHRH agonists, such as with an aromatase inhibitor or as a single-agent, require Compassionate Access Program approval. A recent audit at the BCCA showed that LHRH agonists have been prescribed for preservation of fertility in breast cancer patients undergoing adjuvant chemotherapy, and for ovarian suppression post-chemotherapy. As a reminder, the BCCA does NOT fund LHRH agonists for these indications and patients must fill these prescriptions at the retail pharmacy.

Drug Access Programs – Ipilimumab, Vemurafenib

Ipilimumab:

Ipilimumab (YERVOY®) is a human monoclonal antibody that received Health Canada Notice of Compliance on 01 February 2012 for the indication of unresectable or metastatic melanoma after failure of or intolerance to other systemic therapy. This treatment is not currently funded or administered by the BC Cancer Agency.

Bristol-Myers Squibb (BMS) Canada has implemented the **YERVOY® Access to Hope Program** to enable qualified patients to access ipilimumab via a compassionate supply program (for patients who do <u>NOT</u> have third party insurance coverage) or a co-pay program (for patients who have third party insurance coverage). Prescribers must complete a certification program via the <u>BMS Canada website</u> prior to prescribing the drug. This certification program provides an overview of ipilimumab's efficacy and safety information. To enrol patients into the YERVOY® Access to Hope Program, please complete the Access to Hope Patient Enrolment Form via the above website or call 1-877-967-6626. This information has been updated on the <u>BCCA Patient Assistance Programs website</u>.

Vemurafenib:

Vemurafenib (ZELBORAF®) is a BRAF kinase inhibitor that received Health Canada Notice of Compliance on 15 February 2012 for the treatment of BRAF V600 mutation positive, unresectable or metastatic melanoma. This treatment is not currently funded or dispensed by the BC Cancer Agency.

Hoffmann-La Roche has implemented the **Roche Patient Assistance Program (RPAP)** to enable all qualified patients to access vemurafenib via a compassionate supply program (for patients who do not have third party insurance coverage) or a co-pay program (for patients who have third party insurance coverage). RPAP also offers the coordination of BRAF gene testing. To enrol patients into the RPAP,

DRUG UPDATE

please call 1-888-748-8926. Enrolled patients must arrange with a retail pharmacy to obtain a drug supply. This information has been updated on the <u>BCCA Patient Assistance Programs website</u>.

DRUG SHORTAGE UPDATE: CHLORHEXIDINE

There is a world-wide supply shortage of **chlorhexidine gluconate 0.05% solution**, a surface cleaner used by many BCCA and CON pharmacies to disinfect sterile preparation rooms. The earliest date of release for the next supply is expected to be 03 July 2012. To select an alternative cleaning solution, surfaces to be cleaned along with the properties of the cleaning agent must be taken into consideration. Every time a new cleaning agent is introduced for use, the specific product MSDS (material safety data sheets) must be referred to for any "Hazards Identification" warnings and "First Aid Information".

BCCA Pharmacy has conducted a review of alternative aqueous antibacterial cleaners and recommends the following solutions categorized according to the surface(s) to be cleaned:

For Cleaning of Biological Safety Cabinet (BSC):

Twice Daily Cleaning of All Surfaces of the BSC (First and Last Clean of the Day)

PRODUCTSUPPLIEDCAVICIDE® RTU by MetrexSolution & WipesPERCEPT® RTU by ButchersSolution & WipesPREVENTION® RTU by Accel®Solution & Wipes

Cleaning of Work Surface of the BSC Between Each Preparation

PRODUCT

CAVICIDE® RTU by Metrex

PERCEPT® RTU by Butchers

PREVENTION® RTU by Accel®

WET ONES®

SUPPLIED

Solution & Wipes

Wipes

Wipes

For Cleaning of Final Drug Product Inside the Biological Safety Cabinet:

Cleaning of Final Drug Product Inside the BSC Prior to Removal
PRODUCT SUPPLIED
WET ONES® Wipes

For questions or concerns, please contact the BCCA Pharmacy Chemotherapy Certification Program at rxchemocert@bccancer.bc.ca.

COMMUNITIES ONCOLOGY NETWORK

WORKLOAD REPORTING UPDATE

All Communities Oncology Network (CON) sites are requested to continue to submit workload indicator information related to new patient consultations, chemotherapy visits, and ambulatory care visits to the BCCA Provincial Systemic Therapy Program (PSTP) every fiscal period. This information informs the PSTP of the level of systemic therapy services delivered at each CON site.

The workload definitions and template have been revised and are located on the <u>BCCA CON website</u>. Key changes include:

- Deletion of categories: New Patient Coordination, Oral and Hormonal Chemotherapy Visits –
 prescription information is already captured through claims submitted via the OSCAR (Online System
 for Cancer drugs Adjudication and Reimbursement) system, and does not need to be reported
 separately
- Inclusion/Exclusion Criteria for New Patient Consultations, Parenteral Chemotherapy First Start and Subsequent, Ambulatory Care Visits

Please ensure the new workload template is utilized to report workload starting 01 June 2012.

CANCER DRUG MANUAL

REVISED MONOGRAPHS AND PATIENT HANDOUTS

Highlights of key changes and/or updates to the Monographs and Patients Handouts are listed below.

BCG Monograph:

- Updated antibiotic interaction in Interactions table
- Revised Caution section to include safe handling precautions for the patient
- Revised Solution Preparation and Compatibility section according to current template

Oxaliplatin Monograph:

- Included information on reversible posterior leukoencephalopathy syndrome (RPLS or PRES) in Side Effects section
- Added Children's dosing section as per current template

Oxaliplatin Patient Handout:

 Revised to include signs and symptoms of reversible posterior leukoencephalopathy syndrome in the Emergency section after the Side Effects table

CANCER DRUG MANUAL

<u>PACLitaxel Monograph, Patient Handout and Chemotherapy Preparation and Stability Chart</u> have undergone a comprehensive review to ensure up-to-date information in each document. Expert review was provided by Dr. Caroline Lohrisch (Breast Systemic Group Chair), Kimberly Kuik (Breast Tumour Group Pharmacist), Dr. Anna Tinker (Gynecology Systemic Group Chair) and James Conklin (Gynecology Tumour Group Pharmacist).

PACLitaxel Monograph:

- Removed general management of hypersensitivity reactions from the Hypersensitivity paragraph following the Side Effects table, and added hyperlink to Protocol Summary for Management of Hypersensitivity Reactions to Chemotherapeutic Agents
- Added paragraph on rechallenge after severe hypersensitivity reaction following the Side Effects table
- Removed prescriptive information on gabapentin use for arthralgia and myalgia; specific dosing suggestions for gabapentin are available in the references provided
- Removed management for severe cardiac conduction abnormalities from the Bradycardia and hypotension paragraph
- Removed trastuzumab interaction because of insufficient supporting evidence
- Updated Premedications regimen with current guidelines and references
- Removed PACLitaxel 24-hour infusion in the Dosage section for hepatic failure

PACLitaxel Patient Handout:

Updated according to current template

PACLitaxel Chemotherapy Preparation and Stability Chart:

- Updated to include Hospira brand
- Corrected concentration range for Biolyse brand

DELETED MONOGRAPHS AND PATIENT HANDOUTS

Medroxyprogesterone Injection Patient Handout has been deleted from the BCCA Cancer Drug Manual Drug Index (Patient) as it is no longer a BCCA benefit drug. Please see Benefit Drug List for further details.

BENEFIT DRUG LIST

New Programs

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

 Abiraterone (restricted funding) with Prednisone for symptomatic metastatic castration-resistant prostate cancer in patients not eligible for DOCEtaxel treatment (UGUPABI)

BENEFIT DRUG LIST

DELETED PROGRAMS

The following programs have been removed from the Benefit Drug List effective 01 June 2012 to reflect current practice:

- Leucovorin Eye Drops
- Medroxyprogesterone Injectable please note that the tablet formulation is still available for the treatment of endometrial cancer (GOENDH)

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".

REVISED PROTOCOLS, PPPOS AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED):						
CODE	Protocol	PPPO	Patient Handout Changes		Protocol Title	
CNCCNU				Clarified timing of lomustine dose under Chemotherapy	Lomustine (CCNU) for Treatment of Recurrent Malignant Brain Tumours	
GOENDCAD	Ø			Updated Tests section and Contact Physician; implemented TALLman lettering	Treatment of Primarily Advanced or Recurrent Endometrial Cancer using CARBOplatin and DOCEtaxel	
GOENDCAT				Updated Tests under Return Appointment Orders; implemented TALLman lettering	Treatment of Primary Advanced or Recurrent Endometrial Cancer using CARBOplatin and PACLitaxel	
GOOVCADM	Ø	Ø		Updated Tests section and Contact Physician; implemented TALLman lettering	Primary Treatment of Invasive Epithelial Ovarian, Fallopian Tube and Primary Peritoneal Cancer, with no Visible Residual Tumour (Moderate-High Risk) Using CARBOplatin and DOCEtaxel	
GOOVCADR	Ø			Updated Tests section and Contact Physician; implemented TALLman lettering	Second Line Treatment Using DOCEtaxel and CARBOplatin for Epithelial Ovarian Cancer Relapsing after Primary Treatment	
GOOVCADX		Ø		Updated Tests section and Contact Physician; implemented TALLman lettering	Primary Treatment of Visible Residual (Extreme Risk) Invasive Epithelial Ovarian Cancer Using CARBOplatin and DOCEtaxel	

REVISED PROTOCOLS, PPPOS AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED):							
CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title		
GOOVCATM		V		Updated Tests under Return Appointment Orders; implemented TALLman lettering	Primary Treatment of Invasive Epithelial Ovarian, Fallopian Tube and Primary Peritoneal Cancer, with No Visible Residual Tumour (Moderate-High Risk) Using CARBOplatin and PACLitaxel		
GOOVCATR				Updated Tests under Return Appointment Orders; implemented TALLman lettering	Second Line Treatment Using PACLlitaxel and CARBOplatin for Epithelial Ovarian Cancer Relapsing After Primary Treatment		
GOOVCATX		Ø		Updated Tests under Return Appointment Orders; implemented TALLman lettering	Primary Treatment of Visible Residual (Extreme Risk) Invasive Epithelial Ovarian Cancer in Ambulatory Care Settings Using PACLitaxel and CARBOplatin		
UGUPABI	Ø			Expanded Eligibility and Revised Title	Palliative Therapy for Metastatic Castration Resistant Prostate Cancer Using Abiraterone and Prednisone		
GUPDOC				Clarified PSA testing interval under Return to Appointment Orders	Palliative Therapy for Metastatic Hormone Refractory Prostate Cancer Using DOCEtaxel		
GUPNSAA	Ø			Expanded Eligibility criteria to include use of nilutamide for total androgen blockade	Non-Steroidal Treatment of Prostate Cancer		
ULYRMTN	Ø			Clarified Eligibility section and updated Contact Physician	Maintenance RiTUXimab for Indolent Lymphoma		

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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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	250.712.3900		
Southern Interior	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		
	250.519.5500		
BCCA-Vancouver Island Centre	Toll Free 800.670.3322		

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