Systemic Therapy Update



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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 program effective 01 June 2014:

Lymphoma:

Brentuximab for Relapsed Hodgkin Lymphoma and Systemic Anaplastic Large Cell Lymphoma (ULYBRENTUX) — Brentuximab vedotin is an antibody-drug conjugate composed of a chimeric monoclonal antibody linked to an anti-tubulin agent, monomethylauristatin E (MMAE), which bears similarities to vinca alkyloids. The antibody-drug conjugate targets the CD30 antigen expressed on the cell membrane of Hodgkin lymphoma and anaplastic large cell lymphoma (ALCL). Brentuximab vedotin has been approved at the BCCA for Hodgkin lymphoma and ALCL based on two phase II trials demonstrating promising response rates. In patients with Hodgkin lymphoma relapsing after stem cell transplantation (SCT), brentuximab resulted in an overall response rate (ORR) of 75% and a complete response rate (CRR) of 34%. [Younes A et al. JCO 2012;30:2183-2189] In patients with relapsed or refractory ALCL, brentuximab was associated with an ORR of 86% and a CRR of 57%. [Pro B et al. JCO 2012;30:2190-2196] It is administered as an

EDITOR'S CHOICE

intravenous infusion every 21 days. The most commonly reported toxicities were peripheral neuropathy, nausea, fatigue, neutropenia and diarrhea, but it was quite unusual for these to exceed grade 2 in severity. For further information on the pharmacology of brentuximab vedotin, please see the Cancer Drug Manual section <u>below</u>.

PROVINCIAL SYSTEMIC THERAPY PROGRAM

UPDATED BCCA POLICY III-10 - SYSTEMIC THERAPY TREATMENT DELIVERY PROCESS

The BCCA Systemic Therapy Policy (III-10) on Systemic Therapy Treatment Delivery Process has been updated to allow telephone orders from physicians to hold chemotherapy treatment for reasons of safety. Please note that telephone orders for administration and dosing changes are still not permitted. This information has also been updated in the Nursing Practice References on Administration of Chemotherapeutic Agents (C-252) and Administration of Medications (M-100).

DRUG UPDATE

PACLITAXEL SUPPLY ISSUE

Health Canada has suspended the establishment licence of Biolyse Pharma Corporation due to serious concerns with the manufacturing process. Biolyse is the HealthPro contracted provider of paclitaxel in British Columbia. Health Canada has not identified any health risks to the paclitaxel products already distributed, and has not issued a product recall at this time.

To date, the paclitaxel drug supply has not been affected at the BCCA, but some Communities Oncology Network (CON) centres may face potential supply interruptions in the near future. An alternative supplier, Hospira, can provide paclitaxel at a substantially higher list price.

At this time, the BCCA Provincial Systemic Therapy Program is requesting CON centres that are using paclitaxel supplies acquired from Hospira to submit OSCAR claims at the Biolyse contract price, and to seek reimbursement for the differential cost through the standard HealthPro process.

The BCCA is currently working with HealthPro, HSSBC and various stakeholders to explore strategies for mitigating the potential cost increase, and to minimize supply interruptions. It is also working with the affected tumour groups to explore therapeutic substitutions should this become necessary.

LENALIDOMIDE-RELATED HEPATOTOXICITY

Several recent cases of severe hepatotoxicity have been reported with lenalidomide. These include hepatic failure, fibrosis, cirrhosis, cholestasis, jaundice and non-infectious hepatitis, some of which were fatal. The underlying mechanism is unclear but risk factors may include a history of hepatic and renal disorders, concurrent liver infection, or use of concomitant hepatotoxic medications (e.g. acetaminophen). Therefore, monitoring of liver function is recommended, particularly when the patient has any of the above risk factors. This information has been incorporated into the Cancer Drug Manual monograph and the lenalidomide-containing chemotherapy protocols (UMYLENDEX, ULKMDSL).

CONTINUING PROFESSIONAL DEVELOPMENT

ISMP Webinar (June 6th) – Kadcyla[®] and Herceptin[®]: Look-Alike/Sound-Alike Errors

The Institute for Safe Medication Practices (ISMP) Canada, in partnership with the Canadian Association of Provincial Cancer Agencies (CAPCA), is offering a complimentary webinar to discuss the risk reduction strategies for reducing future medication errors involving trastuzumab emtansine (KADCYLA®) and trastuzumab (HERCEPTIN®).

Date: Friday, June 6th
Time: 9-10 AM PDT

Registration Deadline: Thursday, June 5th

Registration Website: http://www.ismp-canada.org/education/webinars/20140606 capca nc/index.php

Presenters: Susan Walisser, Professional Practice Leader, BC Cancer Agency

Carole Chambers, Director of Pharmacy Services (Cancer Care), Alberta Health Services

Dr. Vishal Kukreti, Clinical Lead, eTools and Technology Cancer Care Ontario

Heather Logan, Executive Director, Canadian Association of Provincial Cancer Agencies

Kathy Vu, Clinical Lead, Safety Initiatives and Formulary Pharmacist

The webinar will be recorded. Please see the <u>ISMP website</u> for further information, including how to access recorded webinars.

NEW BC NURSING CHEMOTHERAPY MAINTENANCE COURSE

The *British Columbia Chemotherapy Maintenance Course* is now available to assist chemotherapy certified nurses in British Columbia to meet continuing competency requirements. This self-directed, online course was developed by the de Souza Institute specifically for nurses who have completed the *BCCA Chemotherapy and Biotherapy Education Program*. It is guided by standards developed by the Canadian Association of Nurses in Oncology (CANO/ACIO) and other agencies.

Course components include:

- a targeted learning plan
- review of essential cancer chemotherapy competencies and new evidence in practice
- a standardized exam
- a self-assessment
- peer feedback
- an evaluation of the learning experience

The first course will begin 14 July 2014. Registration is open until 30 June 2014, and participants are encouraged to register as spaces are limited. For more information, please see the <u>course website</u>.

HIGHLIGHTS FROM INTERNATIONAL SYMPOSIUM ON PHARMACY PRACTICE (ISOPP) 2014

The International Symposium on Pharmacy Practice (ISOPP) 2014 was held in Montreal between April 2 and 5, 2014. The following synopsis highlights three key sessions from this conference which focused on the future directions of cancer treatment.

Oncolytic Viruses as New Cancer Therapeutics - Presenter: Dr. John Bell, Ottawa Hospital Research

CONTINUING PROFESSIONAL DEVELOPMENT

Institute, Canada

Scientists have developed oncolytic viruses to selectively infect and kill cancer cells, while sparing healthy tissues. These viruses are designed to take advantage of a fundamental weakness in cancer cells – the cell death gene that leads to apoptosis, when mutated, is also the gene programmed for viral response. Thus, the mutated gene allows for enhanced viral growth within cancer cells. After tumour cells become infected, the host immune system recognizes the viruses as foreign and attacks them. A study with mice showed that oncolytic viruses have the potential to lead to long-term cancer cell immunity. The use of oncolytic viruses in humans for cancer treatment is still in the investigational stages.

<u>Smart Medicines: The Role of Nanotechnology in the Future of Cancer Treatment</u> – Presenter: Dr. John Lewis, University of Alberta, Canada

Nanotechnology involves the use of nanoparticles for medical and other purposes. The terminology is based on the size of the particles, which usually ranges from 5 to 100 nanometers. Nanoparticles can be utilized for drug delivery to improve properties like solubility, half lives, and tumour selectivity. Polymers, liposomes, metals, and viruses are some of the nanoparticles that are used for drug delivery. Most of the currently marketed nanoparticles for drug delivery use liposomes. For example, liposomal doxorubicin is a formulation of doxorubicin enclosed in liposomes. Liposomes have enhanced permeability in tumour vasculature, but are too large to travel through the capillaries of healthy tissue. Therefore, liposomal doxorubicin is associated with less cardiac toxicity due to reduced cardiac capillary perfusion. It also has a longer circulating half-life because of the addition of poly-ethyleneglycol (PEG) to the liposome, which shields it from phagocytosis by the reticuloendothelial system.

Dr. Lewis discussed future directions with nanoparticles using plant viruses. Plant viruses are structurally similar to human viruses, but are non-pathogenic because they do not replicate in human cells. They are being investigated for use as delivery systems for biological drugs and combination therapies. They may also play a role in therapostics, the combination of diagnostics and therapeutics.

Biosimilars: How Different is Similar - Presenter: Klaus Meier, Heidekreis-Klinikum GmbH, Germany

Subsequent entry biologics (SEBs), also known as biosimilars, are "copycat" versions of biological drugs. The manufacturing process for biological drugs is complex, involving recombinant DNA technology. Manufacturers are only required to disclose information about gene sequencing procedures and DNA vector selection. They are not required to disclose the processes for fermentation and cleaning, or to name the living cells used for protein production. Small differences in any of the undisclosed processes may result in changes in the biological molecule, making it impossible for other manufacturers to reproduce an identical copy of the active ingredient. This is unlike chemically synthesized drugs, where manufacturers are required to disclose all of the processes involved in the synthesis of the drug, allowing other manufacturers to accurately duplicate the process.

Because there are differences in SEB molecules, the manufacturer must undergo a more rigorous process to obtain regulatory approval. This includes the submission of data from phase I and III clinical trials, and post marketing surveillance. The European Medicines Agency (EMA) has recently approved SEBs for filgrastim (G-CSF). The SEB version is highly discounted (by 90%-95% of the original cost), allowing access to individuals who could not otherwise afford the drug. However, the same degree of discount may not be possible for monoclonal antibody SEBs because of higher associated production costs. To date, no SEBs for the treatment of cancer has been approved by Health Canada.

Submitted by: Rhonda Kalyn (BScPharm), CON Pharmacy Educator, BCCA – CSI

CANCER DRUG MANUAL

REVISED MONOGRAPHS AND PATIENT HANDOUTS

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

Brentuximab Interim Monograph has been expanded to a full **Monograph**, and the **Patient Handout** has been completed. Expert review was provided by Dr. Laurie Sehn (Chair, BCCA Lymphoma Tumour Group).

Key updates to the **Monograph** include:

- added Pharmacokinetics table
- expanded on Special Precautions and Dosage Guidelines sections

Highlights of the **Patient Handout** include:

- neutropenia and thrombocytopenia have been reported; infections must be identified and promptly treated; platelet transfusion may be required
- peripheral neuropathy is cumulative and may require dose modification
- other serious side effects include Tumour Lysis Syndrome, Progressive Multifocal Leukoencephalopathy (PML), and Stevens-Johnson Syndrome

Busulfan Monograph:

 Special Populations – added information about the role of therapeutic drug monitoring in the pediatric population

Fulvestrant Monograph:

- Dosing section updated to current dosing recommendations per manufacturer (500 mg per dose, in two injections); added monitoring recommendations to hepatic dosing
- Parenteral Administration table added details pertaining to the rate of injection

TRANSLATED PATIENT HANDOUTS

The following Patient Handouts have been translated into Chinese (traditional) and Punjabi:

- Interferon Alfa-2b Injection
- Irinotecan
- Lenalidomide
- Lomustine

- Melphalan Oral
- Mercaptopurine
- Methotrexate IV
- Procarbazine
- Temozolomide
- Thalidomide
- Vincristine

NEW PROGRAMS The following program has been added to the Benefit Drug List effective 01 June 2014: Protocol Title Protocol Code Benefit Status Treatment of Hodgkin Lymphoma and Anaplastic Large Cell Lymphoma with Brentuximab Restricted

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			
HNAVM			$\overline{\checkmark}$	Treatment of Head and Neck Cancer Using Methotrexate as Standard Therapy			
HNNAVGEM			$\overline{\checkmark}$	Treatment of Loco-regionally Recurrent/Metastatic Nasopharyngeal Cancer Not Amenable for Local Curative Therapy with Gemcitabine			
ULYBRENTUX	$\overline{\checkmark}$	$\overline{\checkmark}$		Treatment of Hodgkin Lymph with Brentuximab	Treatment of Hodgkin Lymphoma and Anaplastic Large Cell Lymphoma with Brentuximab		
LYCHOPRMTX	$\overline{\checkmark}$	$\overline{\checkmark}$		Central Nervous System Prophylaxis with High Dose Methotrexate, CHOP and riTUXimab in Diffuse Large B-Cell Lymphoma			
REVISED PROTOC	COLS, PPPOS A	AND PATIENT I		FFECTED DOCUMENTS ARE CHECKE	ED):		
CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title		
BRAVDOC	\square			Minor typo corrected	Palliative Therapy for Metastatic Breast Cancer using DOCEtaxel		
BRAVEVEX				Dose Modifications for hepatic impairment added	Therapy for Advanced Breast Cancer Using Everolimus and Exemestane		
CNAJTZRT	Ø	Ø		Hepatic Precautions and Dose Modifications added	Concomitant (Dual Modality) and Adjuvant Temozolomide for Newly Diagnosed Malignant Gliomas with Radiation		
UCNBEV			Ø	Dosing calendar clarified	Palliative Therapy for Recurrent Malignant Gliomas Using Bevacizumab With or Without Concurrent Etoposide or Lomustine		

REVISED PROTOCOLS, PPPOS AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED):						
CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title	
CNTEMOZ	$\overline{\checkmark}$	$\overline{\checkmark}$		Hepatic Precautions and Dose Modifications added	Therapy for Malignant Brain Tumours using Temozolomide	
CNTEMOZMD				Hepatic Precautions and Dose Modifications added	Therapy for Malignant Brain Tumours Using Metronomic Dosing of Temozolomide	
UGIOCTLAR	Ø			Eligibility revised on requirement for CAP re-approval	Symptomatic Management of Functional Carcinoid and Neuroendocrine Tumors of the GI Tract Using Octreotide (SANDOSTATIN LAR®)	
UGIPNEVER				Dose Modifications for hepatic impairment added	Palliative Treatment of Advanced Pancreatic Neuroendocrine Tumours using Everolimus	
GOCXCRT	V	Ø		Magnesium infusion time updated	Treatment of High Risk Squamous Carcinoma, Adenocarcinoma, or Adenosquamous Carcinoma of the Cervix with Concurrent CISplatin and Radiation	
GOOVDDCAT	Ø	Ø		Tests and Dose Modifications sections clarified	Primary Treatment of Advanced Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Carcinoma Using CARBOplatin and Weekly PACLitaxel	
GUEVER				Dose Modifications for hepatic impairment added	Therapy for Advanced Renal Cancer Using Everolimus	
GUPLHRH		$\overline{\square}$		Dosing schedule clarified	Therapy for Prostate Cancer Using LHRH Agonist (Goserelin, Leuprolide or Buserelin)	
GUPLHRHA	\square	$\overline{\checkmark}$		Dosing schedule clarified	Therapy for Advanced Prostate Cancer Using LHRH Antagonist	
HNAVP				Treatment cycle clarified	Palliative Chemotherapy for Advanced Head and Neck Squamous Cell Carcinoma with Weekly ClSplatin	
HNNAVP				Treatment cycle clarified, minor typo corrected	Palliative Chemotherapy for Advanced Head and Neck Nasopharyngeal Carcinoma with Weekly ClSplatin	
ULKATOATRA	V			Dosing in obese patients clarified	First-Line Induction and Consolidation Therapy of Acute Promyelocytic Leukemia Using Arsenic Trioxide and Tretinoin (All-Trans Retinoic Acid)	
ULKATOR				Dosing in obese patients clarified	Induction and Consolidation Therapy of Relapsed Acute Promyelocytic Leukemia Using Arsenic Trioxide	
ULKMDSL		Ø		Renal dosing modifications and liver function tests monitoring revised	Therapy of Myelodysplastic Syndrome using Lenalidomide	

REVISED PROTOCOLS, PPPOS AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED):						
CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title	
ULKMFRUX	\square			Eligibility clarified, contact physician revised, restarting dose schema added	Treatment of Symptomatic Myelofibrosis with Ruxolitinib	
LYABVD		Ø		Space to complete total number of cycles added, lower case drug name formatted	Treatment of Hodgkin's Disease with DOXOrubicin, Bleomycin, vinBLAStine and Dacarbazine	
LYCHOP				Space to complete total number of cycles added	Treatment of Lymphoma with DOXOrubicin, Cyclophosphamide, vinCRIStine and predniSONE	
LYCVPPABO		Ø		Space to complete total number of cycles added, TALLman lettering and lower case drug name formatted	Treatment of Hodgkin's Disease with Cyclophosphamide, vinBLAStine, Procarbazine and predniSONE	
LYGDP		Ø		Space to complete total number of cycles added, lower case drug name formatted	Treatment of Lymphoma with Gemcitabine, Dexamethasone and CISplatin (GDP)	
LYGDPR		V		Space to complete total number of cycles added	Gemcitahine Devamethasone and	

The following Lymphoma/Multiple Myeloma chemotherapy protocols have been revised to highlight the importance of confirming baseline test results and the management of hepatitis reactivation.

CODE	Protocol Title
HLHETCSPA	Treatment of Hemophagocytic Lymphohistiocytosis with Etoposide, Dexamethasone and cycloSPORINE
LYALEM	Treatment with Subcutaneous or Intravenous Alemtuzumab for Fludarabine-Refractory B-Chronic Lymphocytic Leukemia (B-CLL) or with Intravenous Alemtuzumab for Previously Untreated T-Prolymphocytic Leukemia (T-PLL)
LYAVBD	Treatment of Hodgkin's Disease with DOXOrubicin, Bleomycin, vinBLAStine and Dacarbazine
ULYBEND	Treatment of Non-Hodgkin Lymphoma with Bendamustine
ULYBENDR	Treatment of Non-Hodgkin Lymphoma with Bendamustine and riTUXimab
LYCCOP	Treatment of Hodgkin's Disease using Cyclophosphamide, vinCRIStine, predniSONE
LYCDA	Treatment of Hairy Cell Leukemia with Cladribine
LYCHLOR	Therapy for Low Grade Lymphoma and Chronic Lymphocytic Leukemia Using Chlorambucil
LYCHOP	Treatment of Lymphoma with DOXOrubicin, Cyclophosphamide, vinCRIStine and predniSONE

CODE	Protocol Title
LYCHOPR	Treatment of Lymphoma with DOXOrubicin, Cyclophosphamide, vinCRIStine, predniSONEand riTUXimab
ULYCLLBEND	Treatment of Relapsed Chronic Lymphocytic Leukemia (CLL) with Bendamustine
LYCODOXMR	Treatment of Burkitt's Lymphoma and Leukemia (ALL-L3) with Cyclophosphamide, vinCRIStine, DOXOrubicin, Methotrexate, Leucovorin (CODOX-M) and riTUXimab
LYCSPA	Cyclosporine for Cytopenias Associated with Lymphoproliferative Disorder of Large Granular Lymphocytes
LYCVP	Treatment of Advanced indolent lymphoma using Cyclophosphamide, vinCRIStine and predniSONE
LYCVPPABO	Treatment of Hodgkin's Disease with Cyclophosphamide, vinBLAStine, Procarbazine and predniSONE
LYCVPR	Treatment of Advanced Indolent Lymphoma using Cyclophosphamide, vinCRIStine, predniSONE and riTUXimab (CVP-R)
LYCYCLO	Therapy of Lymphoma, Hodgkin's Disease, Chronic Lymphocytic Leukemia or Multiple Myeloma Using Cyclophosphamide
LYFLU	Treatment of Low-Grade Lymphoma or Chronic Lymphocytic Leukemia with Fludarabine
LYFLUDR	Treatment of Chronic Lymphocytic Leukemia or Prolymphocytic Leukemia and Relapsed Indolent Lymphoma with Fludarabine and riTUXimab
LYGDP	Treatment of Lymphoma with Gemcitabine, Dexamethasone and CISplatin (GDP)
LYGDPR	Treatment of Lymphoma with Gemcitabine, Dexamethasone and CISplatin (GDP) with riTUXimab
LYHDMRP	Treatment of Primary Intracerebral Lymphoma with High Dose Methotrexate and riTUXimab
LYHDMTXP	Treatment of Primary Intracerebral Lymphoma with High Dose Methotrexate
LYHDMTXR	Treatment of Leptomeningeal Lymphoma or Recurrent Intracerebral Lymphoma with High Dose Methotrexate
LYIT	Treatment of Lymphoma using Intrathecal Methotrexate and Cytarabine
LYIVACR	Treatment of Burkitt's Lymphoma and Leukemia (ALL-L3) with Ifosfamide, Mesna, Etoposide, Cytarabine (IVAC) and riTUXimab
ULYMFECP	Treatment of Cutaneous T-cell Lymphoma (Sézary syndrome) with Extracorporeal Photopheresis
LYPALL	Lymphoma Palliative Chemotherapy
ULYRICE	Treatment of Advanced Stage Large B-Cell Non-Hodgkin's Lymphoma with Ifosfamide, CARBOplatin, Etoposide and riTUXimab
LYRITUX	Treatment of Lymphoma with single agent riTUXimab
ULYRMTN	Maintenance riTUXimab for Indolent Lymphoma
UMYBORPRE	Treatment of Multiple Myeloma Using Bortezomib, Dexamethasone with or without Cyclophosphamide as Induction Pre-Stem Cell Transplant

CODE	Protocol Title
UMYBORREL	Treatment of Relapsed Multiple Myeloma Using Bortezomib, Dexamethasone with or without Cyclophosphamide
UMYCTD	Treatment of Systemic Light-chain (AL) Amyloidosis and Multiple Myeloma Using Cyclophosphamide, Thalidomide and Dexamethasone
МҮМР	Treatment of Multiple Myeloma Using Melphalan and predniSONE
UMYMPBOR	Treatment of Multiple Myeloma using Melphalan, Prednisone and Weekly Bortezomib with the Option of Substituting Cyclophosphamide for Melphalan
ИМҮМРТ	Treatment of Multiple Myeloma Using Melphalan, Prednisone and Thalidomide
UMYTHALID	Therapy of Multiple Myeloma Using 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			

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BCCA-Centre for the North	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		
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