

Systemic Therapy Update



BC Cancer Agency

CARE + RESEARCH

An agency of the Provincial Health Services Authority

January 2013
Volume 16, Number 1

For Health Professionals Who Care For Cancer Patients

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EDITOR'S CHOICE

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

Revised Methotrexate Levels for Initiating Oral Leucovorin (LYCODOXMR, LYHDMRP, LYHDMTXP, LYHDMTXR, MOHDMTX) – The Lymphoma and Miscellaneous Origins Tumour Groups have revised all high-dose methotrexate chemotherapy protocols to raise the threshold of methotrexate serum levels to 0.1 micromol/L from 0.05 micromol/L for discontinuing methotrexate level testing, and initiating oral leucovorin. The change in threshold concentration is a result of a change in immunoassay used worldwide to measure methotrexate serum levels. The new ARK™ homogeneous enzyme immunoassay by ARK Diagnostic Inc. is associated with a higher limit of detection than the previous laboratory method. Inaccuracies have been reported with methotrexate levels below 0.1 micromol/L. This change also applies to the use of the above chemotherapy protocols in patients with other malignancies.

COMMUNITIES ONCOLOGY NETWORK

COMMUNITIES ONCOLOGY NETWORK (CON) SITE CONTACT INFORMATION

Please be reminded that the most up-to-date contact personnel and information for individual CON sites

COMMUNITIES ONCOLOGY NETWORK

should be maintained at all times to facilitate effective communication between cancer team care providers. If the contact information of any CON site is no longer accurate, please email bulletin@bccancer.bc.ca with the correct information. This reminder has been updated on the [BCCA CON website](#).

CANCER DRUG MANUAL

NEW MONOGRAPHS AND PATIENT HANDOUTS

Ipilimumab Patient Handout has been developed. Expert review was provided by Dr. Richard Klasa (Medical Oncologist, Melanoma Tumour Group) and Ms. Kate Yoo (Pharmacist, Melanoma Tumour Group). Ipilimumab is a recombinant, fully human monoclonal antibody which binds to and blocks human cytotoxic T lymphocyte-associated antigen 4 (CTLA-4). Subsequent T-cell activation and proliferation results in lymphocyte infiltration into organ tissues and tumours, which is presumed to lead to tumour cell death. Ipilimumab is indicated for the treatment of unresectable or metastatic melanoma after prior systemic therapy. The following advice is emphasized to highlight the fact that immune-related symptoms cannot be safely self-managed.

“See Your Doctor or Get Emergency Help Immediately and See Your Doctor as Soon as Possible.”

REVISED MONOGRAPHS AND PATIENT HANDOUTS

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

- **Dexrazoxane Monograph’s Dosage Guidelines** section has been revised to clarify the intravenous dosing, renal and hepatic dosing, and children’s dosing.
- **Ipilimumab Interim Monograph** has been updated to the full **Monograph**. Expert review was provided by Dr. Richard Klasa (Medical Oncologist, Melanoma Tumour Group) and Ms. Kate Yoo (Pharmacist, Melanoma Tumour Group).
 - Addition of *Pharmacokinetics* table
 - Expanded *Special Precautions* and *Dosage Guidelines* sections
 - Expanded *Side Effects* section to include symptoms of immune-mediated adverse reactions. These reactions can be non-specific and involve any organ system. An immune-related cause should be considered when symptoms such as diarrhea, increased stool frequency, bloody stool, liver enzyme elevations, rash, endocrinopathies, and neuropathies arise. Because fatalities have been reported, early diagnosis and management of these symptoms are necessary. Patients are strongly advised not to self-treat these symptoms and to report any worsening of symptoms promptly.
- **Trastuzumab Monograph, Patient Handout and Chemotherapy Preparation and Stability Chart** have undergone a comprehensive review. Expert review was provided by Dr. Vanessa Bernstein (Medical Oncologist, Breast Tumour Group), Dr. Bal Johal (Medical Oncologist, Gastrointestinal Tumour Group), and Ms. Kimberly Kuik (Pharmacist, Breast Tumour Group).

CANCER DRUG MANUAL

Monograph:

- Expanded *Pharmacokinetics* section to include differences between metastatic gastric vs. metastatic breast cancer patients.
- Expanded *Special Precautions* section to indicate greater cardiotoxicity risk in patients 65 years of age and older, or those who had prior adjuvant therapy with anthracyclines for early breast cancer.
- Expanded *Side Effects* section to include information on cardiotoxicity risk factors and management.
- Deleted warfarin from *Interactions* section because of no clear association between trastuzumab and bleeding events.
- Updated *Parenteral Administration* section with additional routes of administration.
- Expanded *Dosage Guidelines* section to outline the ongoing discussion on the optimal way to reload trastuzumab after interruption of maintenance therapy.

Patient Handout:

- Separated *Allergic Reactions and Fever, Chills and Flu-Like Illness* due to different management guidelines.

BENEFIT DRUG LIST

REVISED PROGRAMS

The following programs have been revised on the Benefit Drug List effective 01 January 2013:

- Gemcitabine (class I) with CISplatin for the adjuvant treatment of urothelial carcinoma (GUAJPG)
- RiTUXimab (class II) with gemcitabine, dexamethasone and CISplatin for the treatment of lymphoma (LYGDPR)

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
UBRAJACTW	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Hepatic Dose Modifications clarified</i>	Adjuvant Therapy for Early Breast Cancer using DOXOrubicin and Cyclophosphamide followed by Weekly PACLitaxel

REVISED PROTOCOLS, PPPOs AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED):					
CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
BRAJTDC	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Dose Modifications clarified</i>	Adjuvant Therapy for Breast Cancer Using Trastuzumab, DOCEtaxel and Cyclophosphamide
BRAVTRVIN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>PPO reformatted</i>	Palliative Therapy for Metastatic Breast Cancer Using Trastuzumab and Vinorelbine
CNAJTZRT	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Title of Patient Information leaflet on brain radiation updated</i>	Concomitant and Adjuvant Temozolomide for Newly Diagnosed Malignant Gliomas
GICART	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Capecitabine dosing schedule with radiotherapy clarified</i>	Combined Modality Therapy for Carcinoma of the Anal Canal Using Mitomycin, Capecitabine and Radiation Therapy
GICPART	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Capecitabine dosing schedule with radiotherapy clarified</i>	Combined Modality Therapy for Carcinoma of the Anal Canal using CISplatin, Capecitabine and Radiation Therapy
UGIENACTRT	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Lab schedules in Return Appointment Orders clarified</i>	Neoadjuvant Treatment of Esophageal and Gastroesophageal Carcinomas Using CARBOplatin, PACLitaxel and Radiation Therapy
UGIGAVCFT	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Minor typo corrected</i>	Palliative Treatment of Metastatic or Inoperable, Locally Advanced Gastric or Gastroesophageal Junction Adenocarcinoma using CISplatin, Infusional Fluorouracil and Trastuzumab
GIPGEM	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Eligibility corrected to remove CAP requirement if treatment to be continued for 11 cycles or more</i>	Palliative Therapy for Pancreatic Adenocarcinoma, Gallbladder Cancer, and Cholangiocarcinoma Using Gemcitabine
GOCXCRT	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Timing of radiotherapy clarified</i>	Treatment of High Risk Squamous Carcinoma, Adenocarcinoma, or Adenosquamous Carcinoma of the Cervix with Concurrent CISplatin and Radiation
GOENDH	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Megestrol dose clarified</i>	Non-Aromatase Inhibitor Hormonal Treatment of Endometrial Cancer
GOOVETO	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Dilution of 80 mg IV dose clarified; TALLman lettering implemented</i>	Treatment of Relapsed/Progressing Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Carcinoma Using Etoposide
GUAJPG	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Requirement for CAP approval removed; protocol code revised to remove "U" for "undesigned"</i>	Adjuvant Therapy for Urothelial Carcinoma Using CISplatin and Gemcitabine

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

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
HNSAVPAC	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Minor typo corrected</i>	Treatment of Advanced Salivary Gland Cancers With Platinum, DOXOrubicin and Cyclophosphamide
LYCODOXMR	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Threshold of ethotrexate level discontinuing testing and initiating oral leucovorin revised</i>	Treatment of Burkitt's Lymphoma and Leukemia (ALL-L3) with Cyclophosphamide, Vincristine, DOXOrubicin, Methotrexate, Leucovorin (CODOX-M) and RiTUXimab
LYGDPR	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Requirement for CAP approval removed; protocol code revised to remove "U" for "undesignated"</i>	Treatment of Lymphoma with Gemcitabine, Dexamethasone and Cisplatin (GDP) with RiTUXimab
LYHDMRP	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Threshold of methotrexate level for discontinuing testing and initiating oral leucovorin revised</i>	Treatment of Primary Intracerebral Lymphoma with High Dose Methotrexate and RiTUXimab
LYHDMTXP	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Threshold of methotrexate level for discontinuing testing and initiating oral leucovorin revised</i>	Treatment of Primary Intracerebral Lymphoma with High Dose Methotrexate
LYHDMTXR	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Threshold of methotrexate level for discontinuing testing and initiating oral leucovorin revised</i>	Treatment of Leptomeningeal Lymphoma or Recurrent Intracerebral Lymphoma with High Dose Methotrexate
MOHDMTX	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Threshold of methotrexate level for discontinuing testing and initiating oral leucovorin revised</i>	Meningeal Disease (Miscellaneous Tumour Origins) Using High Dose Methotrexate with Leucovorin Rescue
USMAVIPI	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Minor editing in Appendix done</i>	Treatment of Unresectable or Metastatic Melanoma Using Ipilimumab

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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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	888.675.8001 x 678003		requests@bccancer.bc.ca
Pharmacy Professional Practice	250. 519.5574		jkippen@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		
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