

# Systemic Therapy Update



BC Cancer Agency

CARE + RESEARCH

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## EDITOR'S CHOICE

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

**Monitoring Parameters in Chronic Myeloid Leukemia (CML) Therapy** The **Leukemia/Bone Marrow Transplant Group** has revised the protocols and PPPOs for oral agents (dasatinib [ULKCMLD], imatinib [LKCMLI], nilotinib [ULKCMLN]) used in the management of CML to differentiate between the monitoring parameters required for assessing disease progression vs. those for assessing drug toxicity. In some instances, monitoring parameters for dose modification may be less comprehensive and monitoring performed less frequently than when assessing disease progression. These clarifications will help eliminate confusion and assist the pharmacists in determining which parameters are necessary to monitor for dose modification.

### DRUG UPDATE – DEXRAZOXANE COMMERCIALY AVAILABLE

After one year of limited access via the Health Canada Special Access Programme (SAP), dexrazoxane is once again commercially available – now in a new format. ZINECARD<sup>®</sup> 250 mg and 500 mg vials were previously approved as a dexrazoxane-M/6 Sodium Lactate Injection (diluent) combination. Effective November 4<sup>th</sup>, 2010, Health Canada has approved a new format of dexrazoxane which retains its original formulation but no longer requires M/6 Sodium Lactate Injection as a diluent.

The new formulation is reconstituted with Sterile Water for Injection and then requires further dilution using Lactated Ringer's Injection to a final concentration of 1.3-3.0 mg/mL. The Chemotherapy Preparation and Stability Chart has been updated with this new information.

Currently, only the 500 mg vials are available. For further updates on this product, please visit the following website: [http://www.pfizer.ca/en/our\\_products/products/product/197](http://www.pfizer.ca/en/our_products/products/product/197).

## DRUG UPDATE

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**Dexrazoxane** is once again commercially available – now in a new format – after one year of limited access via the Health Canada Special Access Programme (SAP). ZINECARD® 250 mg and 500 mg vials were previously approved as a dexrazoxane-M/6 Sodium Lactate Injection (diluent) combination. Due to a back order of the diluent, access to dexrazoxane had been limited through the SAP until now. Effective November 4<sup>th</sup>, 2010, Health Canada has approved a new format of dexrazoxane which retains its original formulation but no longer requires M/6 Sodium Lactate Injection as a diluent.

The new formulation is reconstituted with Sterile Water for Injection and then requires further dilution using Lactated Ringer's Injection as the final diluent. The Chemotherapy Preparation and Stability Chart has been updated with this new information.

Currently, only the 500 mg vials are available. For further updates on this product, please visit the following website: [http://www.pfizer.ca/en/our\\_products/products/product/197](http://www.pfizer.ca/en/our_products/products/product/197).

**Thalidomide** has become commercially available in Canada since 1 November 2010 (see September issue of Systemic Therapy Update [www.bccancer.bc.ca/HPI/ChemotherapyProtocols/stupdate](http://www.bccancer.bc.ca/HPI/ChemotherapyProtocols/stupdate)). Therefore, all previously ordered thalidomide must be returned to Celgene, the manufacturer, because pharmacists cannot legally dispense thalidomide accessed via the Health Canada's Special Access Programme (SAP). A Celgene representative will contact all affected pharmacies to arrange shipment and reimbursement.

For more information, contact Celgene at tel (289) 291-4796.

**Lapatinib** is licensed by Health Canada for the treatment of HER2+ metastatic breast cancer in the following scenarios:

1. In combination with capecitabine, and after prior treatment with an anthracycline, a taxane, and trastuzumab.
2. In ER+, HER2+ disease, in combination with letrozole as first line hormone therapy.

Lapatinib is not currently funded by the BC Cancer Agency. The manufacturer, GlaxoSmithKline, has an access program (TYKERB® Patient Assistance Program) to help defray the cost of this drug to individual patients (see Patient Assistance Program at [www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Forms](http://www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Forms)). This program will refund:

- 50% of the co-pay fee for patients with third party drug benefit plans
- 20% of the drug cost for patients without third party drug benefits

The cost of lapatinib is also being covered on a case-by-case basis for First Nations Status patients by the NIHB (Non-insured Health Benefits Program). In order to take advantage of this option, physicians should complete the access form for the TYKERB® Patient Assistance Program and indicate as a footnote that the patient has First Nations Status.

## CANCER DRUG MANUAL

**Degarelix Interim Monograph and Patient Handout** have been developed. Degarelix is a luteinizing hormone-releasing hormone (LHRH) *antagonist* used in the treatment of advanced hormone-dependent prostate cancer. Unlike LHRH agonists, degarelix causes testosterone suppression by immediately and reversibly blocking LHRH receptors in the pituitary, reducing the release of luteinizing hormone. A starting dose of 240 mg SC is followed by monthly SC injections of 80 mg. Highlights from these documents include:

- Unlike LHRH agonists, degarelix is not associated with a testosterone surge and clinical flare, and consequently does not require co-administration of anti-androgens.
- QT prolongation has been reported with degarelix. Drug interactions should be considered when prescribing degarelix with concurrent medications.
- Degarelix is supplied as a treatment starter kit and a separate maintenance kit. Follow reconstitution and administration directions carefully for each kit as the instructions vary for the two kits.

Degarelix has also been added to the **Chemotherapy Preparation and Stability Chart**.

**Alemtuzumab Monograph** has been revised to add a citation to the pediatric dosing section.

**Fluorouracil Monograph** has been revised to reformat the Side Effect table and update the Supply and Storage and Solution Preparation and Compatibility sections.

**Letrozole Monograph** has been revised to reformat the Side Effect table and update the Supply and Storage section.

### 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
BRAVTRNAV	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Dose modifications for hematological toxicities clarified</i>	Palliative Therapy For Metastatic Breast Cancer Using Trastuzumab And Vinorelbine
CNAJTZRT	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Timing of radiation clarified</i>	Concomitant and Adjuvant Temozolomide for Newly Diagnosed Malignant Gliomas with Radiation
HNAVFUFA	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Dose modifications for hematological toxicities clarified</i>	5-Fluorouracil and Leucovorin for Recurrent Head and Neck Cancer (Squamous Cell Carcinoma)

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
UHNLCETR	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Timing of Cetuximab with radiation clarified, return appointment section in PPPO clarified</i>	Combined Cetuximab and Radiation Treatment for Locally Advanced Squamous Cell Carcinoma of the Head and Neck
HNLAPRT	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Minor typo in title corrected</i>	Combined Chemotherapy (Cisplatin) and Radiation Treatment for Locally Advanced Squamous Cell Carcinoma of The Head and Neck
HNNAVFUFA	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Dose modifications for hematological toxicities clarified</i>	5-Fluorouracil and Leucovorin for Recurrent Head and Neck Cancer (Nasopharyngeal)
HNNLAPRT	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Minor typo in title corrected</i>	Treatment of Locally Advanced Nasopharyngeal Cancer with Concurrent Cisplatin and Radiation
LULAPERT	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Dosing schedule of premedication clarified</i>	Treatment Of Locally Advanced Non-Small Cell Lung Cancer Using Cisplatin And Etoposide With Radiation Therapy
LUOTPE	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Dosing schedule of premedication clarified</i>	Treatment Of Thymoma With Cisplatin And Etoposide
LUOTPERT	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Dosing schedule of premedication clarified</i>	Treatment Of Thymoma Using Cisplatin And Etoposide With Radiation Therapy
LUPUPE	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Dosing schedule of premedication clarified</i>	Treatment Of Cancer Of Unknown Primary Involving The Thorax With Cisplatin And Etoposide
LUSCPE	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Dosing schedule of premedication clarified</i>	Therapy Of Extensive Stage Small Cell Lung Cancer (SCLC) With Cisplatin And Etoposide
LUSCPERT	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Dosing schedule of premedication clarified</i>	Therapy Of Limited Stage Small Cell Lung Cancer Using Cisplatin And Etoposide With Radiation
LKCMLI	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Scheduling of monitoring parameters clarified</i>	Therapy For Chronic Myeloid Leukemia And Ph+ Acute Lymphoblastic Leukemia Using Imatinib
ULKCMLD	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Scheduling of monitoring parameters clarified</i>	Treatment Of Chronic Myeloid Leukemia And Ph+ Acute Lymphoblastic Leukemia Using Dasatinib
ULKCMLN	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Scheduling of monitoring parameters clarified</i>	Treatment Of Chronic Myeloid Leukemia Using Nilotinib
UMYBORPRE	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Eligibility and Treatment section revised</i>	Treatment of High Risk Multiple Myeloma Using Bortezomib, Dexamethasone With or Without Cyclophosphamide as Induction Pre-Stem Cell Transplant

## WEBSITE RESOURCES AND CONTACT INFORMATION

<b>WEBSITE RESOURCES</b>	<a href="http://www.bccancer.bc.ca">www.bccancer.bc.ca</a>
REIMBURSEMENT AND FORMS: BENEFIT DRUG LIST, CLASS II, BC CANCER AGENCY COMPASSIONATE ACCESS PROGRAM	<a href="http://www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Forms">www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Forms</a>
CANCER DRUG MANUAL	<a href="http://www.bccancer.bc.ca/cdm">www.bccancer.bc.ca/cdm</a>
CANCER MANAGEMENT GUIDELINES	<a href="http://www.bccancer.bc.ca/CaMgmtGuidelines">www.bccancer.bc.ca/CaMgmtGuidelines</a>
CANCER CHEMOTHERAPY PROTOCOLS, PRE-PRINTED ORDERS, PROTOCOL PATIENT HANDOUTS	<a href="http://www.bccancer.bc.ca/ChemoProtocols">www.bccancer.bc.ca/ChemoProtocols</a>
SYSTEMIC THERAPY PROGRAM POLICIES	<a href="http://www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Policies">www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Policies</a>
SYSTEMIC THERAPY UPDATE	<a href="http://www.bccancer.bc.ca/HPI/ChemotherapyProtocols/stupdate">www.bccancer.bc.ca/HPI/ChemotherapyProtocols/stupdate</a>

<b>CONTACT INFORMATION</b>	<a href="http://www.bccancer.bc.ca">www.bccancer.bc.ca</a>	<a href="mailto:bulletin@bccancer.bc.ca">bulletin@bccancer.bc.ca</a>
BC CANCER AGENCY .....	(604) 877-6000 .....	Toll-Free 1-(800) 663-3333
PROVINCIAL SYSTEMIC THERAPY PROGRAM .....	Ext 2247 .....	<a href="mailto:mclin@bccancer.bc.ca">mclin@bccancer.bc.ca</a>
COMMUNITIES ONCOLOGY NETWORK BUSINESS AFFAIRS.....	Ext 2744 .....	<a href="mailto:david.leung@bccancer.bc.ca">david.leung@bccancer.bc.ca</a>
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	Ext 686741	
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VANCOUVER CENTRE (VCC).....	(604) 877-6000 .....	Toll-Free 1-(800) 663-3333
VANCOUVER ISLAND CENTRE (VICC) .....	(250) 519-5500 .....	Toll-Free 1-(800) 670-3322

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