BC Cancer Agency
CARE & RESEARCH

Systemic Therapy Update

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Website access at http://www.bccancer.bc.ca/HPI/ChemotherapyProtocols/stupdate.htm

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IN TOUCH phone list is provided if additional information is needed.

EDITOR'S CHOICE:

ACCESS TO LENALIDOMIDE

Lenalidomide (REVLIMID®) is an oral immunomodulator which is a structural and functional analogue of thalidomide. It is approved by Health Canada for the treatment of patients with transfusion-dependent anemia due to low- and intermediate-1- risk Myelodysplastic syndrome (MDS) and deletion of chromosome (5q). In the US and the European Union, lenalidomide in combination with dexamethasone is also approved for the treatment of patients with multiple myeloma (MM) who have received at least one prior therapy. This indication is currently under review by Health Canada.

Lenalidomide for MDS with 5q deletion is funded by the BCCA on a case-by-case basis:
1. physician needs to obtain approval of the BCCA Compassionate Access Program (CAP) and to register with the RevAid® program
2. physician needs to register the patient with the RevAid® program
The drug would be dispensed at a BCCA regional centre pharmacy, or at a CON centre pharmacy which has been registered with the RevAid® program. Pharmacy registration process includes completion of a group presentation with a Celgene representative and an online education module on the RevAid® program and requirements.

There is currently no funding for lenalidomide for multiple myeloma by the BCCA:
1. physician needs to obtain CAP approval and register with the RevAid® program
2. physician needs to register the patient with the RevAid® program, which would assist the patient to investigate potential for third party funding and compassionate supply by the manufacturer Celgene.
The drug would be dispensed by McKesson Pharmacy to a BCCA regional centre pharmacy, where the patient would obtain the supply.

Until now, some patients have been accessing lenalidomide for multiple myeloma through Celgene's Extended Access Program (EAP). This program is now closing and all enrolled patients will need to be transitioned to the RevAid® program and obtain the drug supply following the same process outlined above for patients with multiple myeloma.

Note that only one month supply of lenalidomide would generally be dispensed at a time. The RevAid® Program can be contacted at 1-888-738-2431. More details on accessing lenalidomide are available on www.bccancer.bc.ca/HPI/ChemotherapyProtocols/sapchart.htm.

ADJUVANT LETROZOLE THERAPY AFTER 5 YEARS OF TAMOXIFEN

The Provincial Systemic Therapy Program currently funds **3 years of letrozole after 5 years of tamoxifen (total of 8 years)**, as adjuvant hormone therapy for early breast cancer ("late switch"). At this time, the additional 2 years of letrozole therapy to complete 5 years of letrozole is not funded by the Provincial Systemic Therapy Program. Despite the lack of funding for extended letrozole therapy, the Breast Tumour Group recommends that postmenopausal women consider taking an additional two years of letrozole after the first three years if they:

- have good tolerance of 3 years of letrozole after tamoxifen
- are in good general health
- have no sign of breast cancer relapse, AND
- have **node positive or "locally advanced"** (e.g., stage III) breast cancer history.

Therefore, women should discuss with their physicians if they are completing 3 years of "late switch" letrozole therapy. Prescriptions for this extended letrozole therapy are not covered by the BC Cancer Agency. Hence, patients will need to be able to afford the approximate monthly cost of $200, or to have private insurance or extended health plans that would cover this cost.

Note that most postmenopausal women with newly diagnosed early breast cancer currently receive a recommendation for **tamoxifen for 2-3 years followed by 2-3 years of AI ("early switch", total of 5 years)**. At this point, it is unclear whether they should receive more than 2-3 years of therapy with AI; extension beyond the total of 5 years of adjuvant therapy is not funded by the Provincial Systemic Therapy Program. These women and those who are completing 5 years of an AI ("upfront use") may contact their previous oncologist at the BC Cancer Agency to see if they could participate in a clinical trial examining the best duration of AI treatment.

MA17 was the clinical trial that was designed to evaluate the benefit of 5 years of letrozole, after tamoxifen for 5 years. An interim analysis at 3 years was positive for letrozole therapy, therefore, the study was stopped early and patients were unblinded. Many women who had not been on letrozole opted to start taking it at that time. Therefore, although there is **indirect evidence** to suggest longer therapy may be advantageous, the planned complete 5 year comparison of letrozole *vs.* no letrozole will never be reported. From other adjuvant studies we know that 5 years of treatment with an AI (e.g., letrozole), without prior tamoxifen treatment is safe and usually well-tolerated.

Submitted by:
Mário de Lemos, PharmD, MSc (Oncol)
Provincial Drug Information Coordinator
BC Cancer Agency

Reviewed by:
Susan Ellard, MD
Medical Oncologist,
Centre for the Southern Interior – BC Cancer Agency

HIGHLIGHTS OF CHANGES IN PROTOCOLS AND PROVINCIAL PRE-PRINTED ORDERS (PPPOS)

The **Gastrointestinal Tumour Group** has introduced a new protocol for adjuvant chemotherapy for resected pancreatic cancer (GIPAJGEM) and a new chemotherapy for advanced gastric cancer with epirubicin, cisplatin and capecitabine (UGIGAVECC). The gemcitabine in the GIPAJGEM protocol is a class II benefit indication, while the UGIGAVECC protocol requires BCCA Compassionate Access Program approval. In addition, the tumour group has revised several existing treatment protocols and PPPOs:

- oxaliplatin starting dose has been decreased to 85 mg/m^2 for UGIFOLFOX and UGIFFOXB
- dose modification schema has been revised for all FOLFOX-based protocols to be consistent with the clinical trial CRC.2
- the optional use of calcium and magnesium infusion has been added to prevent or reduce oxaliplatin-related neuropathy in patients with metastatic colorectal cancer

Dose Modifications for Methotrexate have been updated by the **Breast Tumour Group** and **the Genitourinary Tumour Group** to include more details on dose adjustment in patients with renal dysfunction.

Blood Pressure Monitoring for Sunitinib and Sorafenib have been updated by the Genitourinary, Gastrointestinal and Sarcoma Tumour Groups. The revisions include consistent information for the protocols, PPPOs and protocol specific patient handouts (UGUSUNI, UGUSORAF, UGIFORAF, USAAVGS).

The **Breast Tumour Group** has revised the **adjuvant trastuzumab protocols**, including a new reference to the recommendations of the Canadian Trastuzumab Working Group on cardiac management during adjuvant trastuzumab therapy.

CANCER DRUG MANUAL

Lenalidomide Monograph and Patient Handout have been developed. Expert review was provided by Dr. Kevin Song (Leukemia/BMT Tumour Group). An analogue of thalidomide, lenalidomide is teratogenic. Readers are encouraged to review the monograph and Editor's Choice section ("Access to Lenalidomide") of this issue of the Systemic Therapy Update for details regarding appropriate precautions and the manufacturer's RevAid® program.

Thiotepa Monograph and Patient Handouts have been completely revised. Expert review was provided by Dr. Susan Ellard (Breast Tumour Group). Highlights of **monograph** changes include:

- potential interactions between thiotepa with aprepitant and phenytoin added
- details regarding intrathecal administration added: systemic toxicities are infrequent with the exception of myelosuppression; neurologic toxicities including aseptic chemical meningitis, characterized by fever, headache, nausea and vomiting, meningismus, photophobia, and dehydration may occur; better drug exposure may be achieved if given IV because thiotepa diffuses rapidly out of the CNS and the active metabolite TEPA is not formed in the CNS

Highlights of **handout** changes include:

- injection handout: addition of phenytoin interaction as well the following side effects and their management: fatigue, skin rash, fever, headache, and loss of appetite
- intrathecal handout: has been created
- intravesical bladder handout: deleted as this route is not used at the BCCA

Cisplatin Monograph now includes details regarding mannitol's potential involvement in some sensitivity reactions; mannitol is given with cisplatin to prevent nephrotoxicity.

Sunitinib Monograph now includes directions for compounding an oral liquid formulation for patients unable to swallow the capsules.

Chemotherapy Preparation and Stability Chart has been updated for the **thiotepa** section:

- addition of syringe information including stability and caution that solution is hypotonic and must be further diluted with NS prior to use
- addition of recommendation to protect vial and product from light
- clarification of when filtration through 0.22 micron filter should occur
- precaution added to not use if product precipitates or remains opaque

SAFE MEDICATION PRACTICES

As part of the accreditation standard, staff should be routinely made aware of a list of abbreviations that should not be used. The Institute for Safe Medication Practices (ISMP) of Canada has published a list of abbreviations, symbols and dose designations that are being frequently misinterpreted and involved in medication errors:

Abbreviation	Intended Meaning	Problem	Correction
U	unit	Mistaken for "0", "4", or cc.	Use "unit".
IU	international unit	Mistaken for "IV" or "10".	Use "unit".
Abbreviations for drug names		Misinterpreted because of similar abbreviations for multiple drugs; e.g., MS, MSO_4 (morphine sulphate), Mg SO_4 (magnesium sulphate) may be confused for one another.	Do not abbreviate drug names.
QD QOD	Every day Every other day	QD and QOD have been mistaken for each other, or as "qid". The Q has also been misinterpreted as "2".	Use "daily" and "every other day".
OD	Every day	Mistaken for "right eye" (OD = oculus dexter).	Use "daily".
OS, OD, OU	Left eye, right eye, both eyes	May be confused with one another.	Use "left eye", "right eye" or "both eyes".
D/C	Discharge	Interpreted as "discontinue whatever medications follow" (typically discharge medications).	Use "discharge".
cc	cubic centimetre	Mistaken for "u" (units).	Use "mL" or "millilitre".
µg	microgram	Mistaken for "mg" resulting in one thousand-fold overdose.	Use "mcg".
Symbols	**Intended Meaning**	**Problem**	**Correction**
@	at	Mistaken for "2" or "5".	Use "at".
> <	Greater than Less than	Mistaken for "7" or the letter "L". Confused with each other.	Use "greater than"/"more than" or "less than"/"lower than".
Dose Designation	**Intended Meaning**	**Problem**	**Correction**
Trailing zero	*X*.0 mg	Decimal point is overlooked resulting in 10-fold dose error.	Never use a zero by itself after a decimal point. Use "*X* **mg**".
Lack of leading zero	. *X* mg	Decimal point is overlooked resulting in 10-fold dose error.	Always use a zero before a decimal point. Use "**0.** *X* mg".

Adopted from ISMP Canada Safety Bulletin, 16 July 2006 (www.ismp-canada.org/dangerousabbreviations.htm).

DRUG UPDATE – SORAFENIB ASSISTANCE PROGRAM

The Assistance Bayer Canada (ABC) Nexavar® Program has a toll-free phone line answered by reimbursement specialists who can help investigate if the patient is covered by private drug plan and whether financing is needed for co-payments and deductibles. For more information, call toll-free 1-866-246-7796 (British Columbia, Alberta, Saskatchewan & Manitoba) or 1-800- NEXAVAR (1-800-639-2827).

Sorafenib is currently funded by the BC Cancer Agency for advanced renal cell carcinoma after cytokine failure (UGUSORAF) and for advanced hepatocellular carcinoma (UGISORAF).

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 and revised protocols, PPPOs and patient handouts for this month are listed below. Protocol codes for treatments requiring "Compassionate Access Program" (previously Undesignated Indication 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
UGIGAVECC	☑	☑	☐	Palliative Therapy for Metastatic of Locally Advanced Gastric or Esophagogastric Cancer Using Epirubicin, Cisplatin and Capecitabine
GIPAJGEM	☑	☑	☐	Adjuvant Chemotherapy for Pancreatic Adenocarcinoma Using Gemcitabine
ULKMDSL	☑	☐	☐	Therapy of Myelodysplastic Syndrome using Lenalidomide

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

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
BRAJACTT	☑	☑	☐	*Cardiac management and treatment interruptions clarified, date added to second page of PPPO*	Adjuvant Therapy for Breast Cancer using Doxorubicin and Cyclophosphamide followed by Paclitaxel and Trastuzumab
BRAJACTTG	☑	☑	☐	*Cardiac management and treatment interruptions clarified, date added to second page of PPPO*	Adjuvant Therapy for Breast Cancer using Dose Dense Therapy: Doxorubicin and Cyclophosphamide followed by Paclitaxel and Trastuzumab
BRAJCMF	☑	☑	☐	*Dose modifications for renal and hepatic dysfunction added, contact physician revised, title clarified*	Adjuvant Therapy of High Risk Breast Cancer using Cyclophosphamide, Methotrexate and Fluorouracil

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
BRAJCMFPO	☑	☑	☐	*Dose modifications for renal and hepatic dysfunction added, contact physician revised, title clarified*	Adjuvant Therapy for High-Risk Breast Cancer using Cyclophosphamide (oral), Methotrexate and Fluorouracil
UBRAJDCT	☑	☐	☐	*Cardiac management and treatment interruptions clarified*	Adjuvant Therapy for Breast Cancer Using Docetaxel, Carboplatin, and Trastuzumab
BRAJDTFEC	☑	☐	☐	*Cardiac management and cyclophosphamide renal dose modification parameters clarified, date added to second page of PPPO*	Adjuvant Therapy for Breast Cancer Using Docetaxel and Trastuzumab, and Fluorouracil, Epirubicin and Cyclophosphamide
BRAJTR	☑	☐	☐	*Cardiac management and treatment interruptions clarified*	Adjuvant Therapy for Breast Cancer using Trastuzumab (HERCEPTIN®) following the Completion of Chemotherapy (Sequential)
BRLAACDT	☑	☐	☐	*Cardiac management and treatment interruptions clarified, date added to second page of PPPO*	Treatment of Locally Advanced Breast Cancer using Doxorubicin and Cyclophosphamide followed by Docetaxel (TAXOTERE®) and Trastuzumab
BRAVCMF	☑	☑	☐	*Dose modifications for renal and hepatic dysfunction added, contact physician revised*	Palliative Therapy for Advanced Breast Cancer using Cyclophosphamide, Methotrexate and Fluorouracil
BRAVCMFPO	☑	☐	☐	*Dose modifications for renal and hepatic dysfunction added, contact physician revised*	Palliative Therapy for Advanced Breast Cancer using Cyclophosphamide (oral), Methotrexate and Fluorouracil
BRAVTR	☑	☐	☐	*Eligibility clarified*	Palliative Therapy for Metastatic Breast Cancer using Trastuzumab
UGIAJFFOX	☑	☐	☐	*Dose modifications revised*	Adjuvant Combination Chemotherapy for Stage III Colon Cancer Using Oxaliplatin, 5-Fluorouracil and Folinic Acid (Leucovorin)
UGICAPIRI	☑	☑	☐	*Starting dose and dose level revised, dosing for age > 65 deleted*	First Line Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Irinotecan and Capecitabine in Patients Unsuitable for GIFOLFIRI
UGICAPOX	☑	☑	☐	*Option of calcium and magnesium added, starting dose of oxaliplatin decreased, dose modifications revised, venous occlusive disease and hemolytic uremic syndrome added to Precautions*	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Oxaliplatin, and Capecitabine
UGICIRB	☑	☑	☐	*Starting dose and dose level revised, dosing for age > 65 deleted*	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Irinotecan, Bevacizumab and Capecitabine

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
UGICOXB	☑	☑	☐	*Option of calcium and magnesium added, treatment duration and maximum dose of bevacizumab revised, venous occlusive disease and hemolytic uremic syndrome added to Precautions*	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Oxaliplatin, Bevacizumab and Capecitabine
UGIFFIRB	☐	☑	☐	*Typo in 24 hr urine parameters corrected*	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Irinotecan, Fluorouracil, Folinic Acid (Leucovorin) and Bevacizumab
UGIFFOXB	☑	☑	☐	*Option of calcium and magnesium added, starting dose of oxaliplatin decreased, treatment duration and maximum dose of bevacizumab revised, dose modifications revised, venous occlusive disease and hemolytic uremic syndrome added to Precautions*	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Oxaliplatin, 5-Fluorouracil, Folinic Acid (Leucovorin) and Bevacizumab
UGIFOLFOX	☑	☑	☐	*Option of calcium and magnesium added, starting dose of oxaliplatin decreased, dose modifications revised, venous occlusive disease and hemolytic uremic syndrome added to Precautions*	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Oxaliplatin, 5-Fluorouracil and Folinic Acid (Leucovorin)
UGIRAJFFOX	☑	☐	☐	*Dose modifications revised, interactions with warfarin deleted from Precautions*	Adjuvant Combination Chemotherapy for Stage III Rectal Cancer Using Oxaliplatin, 5-Fluorouracil and Folinic Acid (Leucovorin)
UGISORAF	☑	☑	☑	*Return appointment for blood pressure monitoring clarified*	Therapy for Advanced Hepatocellular Carcinoma Using Sorafenib (NEXAVAR®)
GUMVAC	☑	☐	☐	*Methotrexate renal dosing adjustment added*	Therapy for Transitional Cell Cancers of the Urothelium using Methotrexate, Vinblastine, Doxorubicin and Cisplatin
UGUSORAF	☑	☑	☑	*Return appointment for blood pressure monitoring clarified*	Palliative Therapy for Renal Cell Carcinoma Using Sorafenib (NEXAVAR®)
UGUSUNI	☑	☑	☑	*Return appointment for blood pressure monitoring clarified*	Palliative Therapy for Renal Cell Carcinoma Using Sunitinib
UGUTEM	☐	☑	☐	*Timing for premedication clarified*	Therapy for Advanced Renal Cancer Using Temsirolimus

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
HNM	☑	☐	☐	*Dose modifications for renal dysfunction clarified*	Head and Neck Cancer Using Methotrexate as Standard Therapy
USAAVGS	☑	☑	☑	*Return appointment for blood pressure monitoring clarified*	Second Line Treatment of Advanced C-kit Positive Gastrointestinal Stromal Cell Tumours (GIST's) After Imatinib Using Sunitinib (SUTENT®)

CONTINUING EDUCATION

National Oncology Pharmacy Symposium (NOPS) will be held by the Canadian Association of Pharmacy in Oncology on **17-19 October, 2008** at the Hyatt Regency in Calgary, Alberta. The year's theme is "*New Frontiers in Oncology Pharmacy*". Conference information and registration is available on www.capho.org/nops/2008/.

BC Cancer Agency Annual Cancer Conference is now opened to registration. This 3-day conference, to be held on **20-22 November** at the Westin Bayshore Resort & Marina in Vancouver, is the BC Cancer Agency's premier professional development, learning and networking event.

This year's theme, "*Survivorship: Creating It, Managing It"*, will explore at the issues and challenges of living after cancer, how wellbeing and health is impacted by surviving the cancer experience, and how we can work to minimize and mitigate current and future problems to ensure survivorship means 'living well' after cancer.

Details on the agenda and registration are available at: www.bccancer.bc.ca/HPI/ACC2008.

WEBSITE RESOURCES

The following are available on the BC Cancer Agency website (www.bccancer.bc.ca) under the Health Professionals Info section:

REIMBURSEMENT AND FORMS: BENEFIT DRUG LIST, CLASS II, COMPASSIONATE ACCESS PROGRAM (UNDESIGNATED INDICATION)	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	www.bccancer.bc.ca/ChemoProtocols
CANCER CHEMOTHERAPY PRE-PRINTED ORDERS	www.bccancer.bc.ca/ChemoProtocols under the index page of each tumour site
SYSTEMIC THERAPY PROGRAM POLICIES	www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Policies
UNCONVENTIONAL CANCER THERAPIES MANUAL	under Patient/Public Info, Unconventional Therapies

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IN TOUCH	www.bccancer.bc.ca	bulletin@bccancer.bc.ca
BC CANCER AGENCY	(604) 877-6000	Toll-Free 1-(800) 663-3333
PROVINCIAL SYSTEMIC THERAPY PROGRAM	Ext 2247	atomash@bccancer.bc.ca
COMMUNITIES ONCOLOGY NETWORK	Ext 2744	jvenkate@bccancer.bc.ca
UPDATE EDITOR	Ext 2288	mdelemos@bccancer.bc.ca
COMMUNITIES ONCOLOGY NETWORK PHARMACIST	Ext 6277	laurelk@bccancer.bc.ca
COMMUNITIES ONCOLOGY NETWORK PHARMACY EDUCATORS		www.bccancer.bc.ca/RS/CommunitiesOncologyNetwork/Educators/Pharmacists/
COMPASSIONATE ACCESS PROGRAM OFFICE	Ext 6277 Fax (604) 708-2026	cap_bcca@bccancer.bc.ca
DRUG INFORMATION	Ext 6275	druginfo@bccancer.bc.ca
EDUCATION RESOURCE NURSE	Ext 2638	nursinged@bccancer.bc.ca
NURSING PROFESSIONAL PRACTICE	Ext 2623	ilundie@bccancer.bc.ca
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VANCOUVER ISLAND CENTRE (VICC)	(250) 519-5500	Toll-Free 1-(800) 670-3322