BC Cancer Agency
CARE & RESEARCH

Systemic Therapy Update

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

INSIDE THIS ISSUE

EDITOR'S CHOICE:

2009/10 NEW DRUG PROGRAMS

The Provincial Systemic Therapy Program of the BC Cancer Agency is pleased to announce several new drug programs for 2009/10. These programs will be implemented once the corresponding treatment protocols, patient information materials and pre-printed orders have been developed and made available on the BC Cancer Agency web site (www.bccancer.bc.ca). The implementation dates of the new programs will be announced in the Systemic Therapy Update (see Highlights of Changes in Protocols and List of New and Revised Protocols for more details).

Funded Programs

Tumour Group	Program	Benefit Status	Expected Implementation Date
Breast	Adjuvant **docetaxel** and **cyclophosphamide** chemotherapy for early breast cancer as an alternative to anthracycline-based chemotherapy (BRAJDC)	Class II (docetaxel)	June 2009
Gastrointestinal	**Panitumumab** as third-line therapy for metastatic colorectal cancer with wild-type K-ras	Case-by-case review via CAP	July 2009

Tumour Group	Program	Benefit Status	Expected Implementation Date
Genitourinary	**Total Androgen Blockade** for advanced prostate cancer with *(GUPNSAA)* ▪ **LHRH agonist** and **bicalutamide (preferred)** or flutamide ▪ orchiectomy and **bicalutamide (preferred)** or flutamide	class I (LHRH agonist, bicalutamide, flutamide)	July 2009
Leukemia	**Nilotinib** as an alternative to dasatinib for chronic myeloid leukemia in chronic phase or accelerated phase resistant or intolerant to imatinib (ULKCMLN)	Case-by-case review via CAP	July 2009
Myeloma	**Lenalidomide** and **dexamethasone** as second or third line treatment of relapsed or refractory multiple myeloma (UMYLENDEX)	Case-by-case review via CAP	June 2009

*CAP = BC Cancer Agency Compassionate Access Program (https://cap.phsa.ca/)

The following program is still under review:

Tumour Group	Program
Gastrointestinal	**Cetuximab with irinotecan** as third-line therapy for metastatic colorectal cancer with wild-type K-ras

The following programs are not funded for 2009/10:

Tumour Group	Program	Priorities and Evaluation Committee Comments
Head and Neck	**Cetuximab** for locoregionally recurrent/metastatic squamous cell carcinoma of the head and neck	High level evidence is provided for the use cetuximab in the palliative head and neck cancer. However, the benefits are small and the incremental costs are high.
Neuro-Oncology	Dose intensive **temozolomide** for relapsed malignant gliomas	There is good biologic rationale and some emerging phase II data in favour of dose-intense temozolomide. Phase III evidence is awaited to establish this as standard therapy.
Neuro-Oncology	**Bevacizumab** and **irinotecan** for relapsed malignant gliomas	The accumulating evidence is compelling and there are grounds to be cautiously optimistic. However, bevacizumab is a new agent in this disease site so “it is very important that phase III evidence is awaited to better define the benefit and toxicity of this agent in a randomized manner.

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

The **Lymphoma/Myeloma Tumour Group** has introduced a funded program of **lenalidomide** with **dexamethasone** as a second and third line treatment in patients with multiple myeloma (UMYLENDEX). The use of lenalidomide will require a CAP approval. For patients currently receiving lenalidomide with CAP approval for myeloma through Celgene's Multiple Myeloma REVLIMID® Access Program (MM-RAP) or the Vancouver Hospital's Expanded Access Program (EAP), they will continue with the current process until BCCA funding begins on 1 July. BCCA funding will also begin on 1 July for patients currently receiving lenalidomide with CAP approval for myelodysplastic syndrome (MDS) with 5q deletion through Celgene's compassionate supply.

The Tumour Group has also revised all rituximab-based protocols to allow more flexible acetaminophen dosing (650-1000 mg) as pre-medication. It has been noted that a number of patients bring in the extra strength version (500 mg), making the previous pre-medication dose of 650 mg impossible.

The **Breast Tumour Group** has revised the adjuvant **docetaxel** and cyclophosphamide protocol for high risk, node negative or node positive breast cancer (**BRAJDC**):

- requirement for CAP approval has been replaced by class II benefit for docetaxel
- eligibility has been expanded to include patients without contraindications to anthracycline-based chemotherapy

The **Lung Tumour Group** has revised the **erlotinib** protocol as second and third line treatment for advanced non-small cell lung cancer (**LUAVERL**). The requirement for CAP approval has been replaced by class II benefit.

The **Gastrointestinal Tumour Group** has developed new patient information materials for several protocols (**GIAJFL**, **GIAVFL**, **GIFUFA**).

CANCER DRUG MANUAL

Cetuximab Monograph and Patient Handout have been developed. Expert review was provided by Dr. Sanjay Rao (GI Tumour Group). Cetuximab is a chimeric monoclonal antibody which binds to the human epidermal growth factor receptor (EGFR). Highlights of the new monograph and handout include the following:

- Infusion reactions are common, particularly with the first dose, and may require pre-medication.
- Caution is advised in patients with a history of cardiac or pulmonary disease.
- Most frequently reported side effects include: skin disorders (i.e., acneiform rash, hair changes, dry skin, and nail changes), fatigue/malaise, and gastrointestinal symptoms (i.e., nausea, diarrhea, constipation, anorexia, and abdominal pain).
- Sun exposure may exacerbate dermatologic toxicity, and should be avoided during treatment and for 8 weeks following.
- Hypomagnesemia is common and can manifest as severe fatigue, irritability, paresthesias, and hypocalcemia. Electrolytes should be monitored during treatment and for 8 weeks following, and should be replaced as necessary.

Erlotinib Patient Handout has been updated to include the interaction with omeprazole (LOSEC®) that previously appeared only in the monograph.

Leuprolide Monograph has been revised to reflect the discontinuation by the manufacturer of the 7.5 mg and 30 mg formats of the ELIGARD® product.

Chemotherapy Preparation and Stability Chart has been updated:

- **Cetuximab:** a new entry has been created. A 0.2 or 0.22 micron in-line filter is recommended for administration. It is also noted that the solution may contain white particulates, and that these do not affect product quality.
- **Gemcitabine:** information for the Hospira brand of gemcitabine has been added.

FREQUENTLY ASKED QUESTION – PHARMACY ACCESS TO LENALIDOMIDE

Question

What is the process for obtaining REVLIMID® (lenalidomide)?

Answer

Lenalidomide is available in Canada for treatment of multiple myeloma and for myelodysplastic syndrome (MDS) with the deletion 5q cytogenetic abnormality. Due to its potential teratogenic effects, lenalidomide must be obtained through RevAid, a distribution program mandated by Health Canada to help prevent fetal exposure as well as to monitor for other potential complications (e.g., neutropenia, thrombocytopenia, deep vein thrombosis, pulmonary embolism).

The method for obtaining lenalidomide depends on whether the cost of the drug is being covered by the BC Cancer Agency or by Celgene:

Coverage	***Eligibility***	***Dispensing process***
Funded by BC Cancer Agency	▪ approved by CAP for MDS with 5q deletion on 1 August 2008 or later ▪ approved by CAP for relapsed or refractory multiple myeloma on 1 June 2009 or later	Lenalidomide can be dispensed by BCCA or CON Hospital pharmacies which have completed the RevAid program (see below).
Supplied by Celgene on a compassionate basis*	▪ started on lenalidomide before 1 August 2008 for MDS with 5q deletion ▪ started on lenalidomide before 1 June 2009 for multiple myeloma (Multiple Myeloma REVLIMID® Access Program [MMRAP])	McKesson Specialty Prescription Services dispenses lenalidomide on behalf of Celgene and ships it directly to the BCCA. McKesson pharmacists look after all of the steps required for the RevAid program.

CAP = BC Cancer Agency Compassionate Access Program

*This will end on 1 July, when BCCA funding will begin for patients receiving lenalidomide approved by CAP for:

- MDS with 5q deletion since 1 August 2008, or
- relapsed or refractory multiple myeloma since 1 June 2009

All pharmacies need to follow the **RevAid procedures** to be able to dispense lenalidomide.

Registration and certification

1. Pharmacies must register for RevAid (tel: 1-888-738-2431) to obtain a pharmacy identification number and pass code to access the RevAid website.

2. Pharmacists dispensing lenalidomide must complete an online certification program followed by a proficiency test.

Dispensing prescription

1. Pharmacists must have a confirmation number for each prescription dispensed. This is currently obtained by phone (1-888-738-2431) but may be available via the RevAid website (www.revaid.ca) in the near future. Before contacting RevAid for a confirmation number:
   a. Be ready to provide the RevAid pharmacy identification number.
   b. Confirm that the patient and the prescribing physician are registered with RevAid by obtaining their ID numbers from the lenalidomide prescription; contact the physician to provide this information if it is missing. If the prescribing physician is away, try contacting another physician who is registered with RevAid.
   c. Confirm the Patient Risk Type (i.e. female of childbearing potential, female not of childbearing potential, male) and document on the Patient Specific Log Sheet.
   d. Contact the patient **every time** lenalidomide is dispensed and counsel the patient using the RevAid® Pharmacist's Counseling Checklist for the appropriate risk type.
2. Dispense the prescription no later than 24 hours after obtaining the confirmation number.The RevAid patient information sheet must be provided with each prescription. RevAid provides different patient information sheets for MDS and for myeloma.

Submitted by:
Rhonda Kalyn, BSP
Pharmacy CON Educator
Centre for the Southern Interior – BC Cancer Agency

Reviewed by:
Linda Hamata, BSc(Pharm)
Special Access Program Pharmacist
Vancouver Centre – BC Cancer Agency

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
GIAJFL	☐	☐	☑	Adjuvant therapy of colon cancer using Fluorouracil Injection and Infusion, and Folinic Acid (Leucovorin)
GIAVFL	☐	☐	☑	Palliative chemotherapy for metastatic colorectal cancer using Fluorouracil Injection and Infusion, and Folinic Acid (Leucovorin)
GIFUFA	☐	☐	☑	Palliative chemotherapy of advanced colorectal cancer using Flurouracil and Folinic Acid (Leucovorin)
LUSCPE	☐	☐	☑	Treatment of Extensive Stage Small Cell Lung Cancer (SCLC) with Cisplatin and Etoposide
UMYLENDEX	☐	☐	☑	Therapy of Multiple Myeloma Using Lenalidomide with Dexamethasone

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

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
BRAJDC	☑	☑	☐	*Requirement for BCCA Compassionate Access Program replaced by Class II benefit for docetaxel, eligibility revised, new reference added*	Adjuvant Therapy for Breast Cancer Using Docetaxel and Cyclophosphamide
BRAJTR	☑	☑	☐	*Eligibility revised*	Adjuvant Therapy for Breast Cancer using Trastuzumab following the Completion of Chemotherapy (Sequential)
CNAJTZRT	☑	☑	☐	*Exclusions, Tests, Dose Modifications for hepatic functions clarified*	Concomitant and Adjuvant Temozolomide for Newly Diagnosed Malignant Gliomas with Radiation
CNTEMOZ	☑	☑	☐	*Exclusions, Tests, Dose Modifications for hepatic functions clarified*	Therapy for Malignant Brain Tumours using Temozolomide
GIPAJGEM	☐	☑	☐	*Reminder for Class II requirement added*	Adjuvant Chemotherapy for Pancreatic Adenocarcinoma Using Gemcitabine
GIPGEM	☐	☑	☐	*Number of treatment cycles clarified*	Palliative Therapy for Pancreatic Adenocarcinoma, Gallbladder Cancer, and Cholangiocarcinoma Using Gemcitabine
GOOVETO	☑	☐	☐	*Typo deleted from Eligibilty*	Treatment of Relapsed/Progressing Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Carcinoma Using Etoposide
GOOVLDOX	☐	☑	☐	*Dilution volume clarified*	Treatment of Relapsed/Progressing, Epithelial Ovarian, Primary Peritoneal Or Fallopian Tube Carcinoma Using Pegylated Liposomal Doxorubicin
GUBPWRT	☐	☑	☐	*Weekly treatment schedule clarified*	Treatment of Locally Advanced Bladder Cancer with Weekly Cisplatin and Concurrent Radiation
HNLANPRT	☐	☑	☐	*Weekly treatment schedule clarified*	Treatment of Locally Advanced Nasopharyngeal Cancer with Concurrent Cisplatin and Radiation
HNPE	☑	☐	☐	*Contact physician updated*	Intensive cisplatin and etoposide chemotherapy for recurrent and metastatic head and neck cancer
LUAVERL	☑	☑	☐	*Requirement for BCCA Compassionate Access Program replaced by Class II benefit*	Treatment of Advanced Non-Small Cell Lung Cancer (NSCLC) with Erlotinib
LYABVD	☐	☑	☐	*Dose modification section modified*	Treatment of Hodgkin's disease with Doxorubicin, Bleomycin, Vinblastine and Dacarbazine
LYCHOP	☐	☑	☐	*Dose modification section modified*	Treatment of Lymphoma with Doxorubicin, Cyclophosphamide, Vincristine and Prednisone

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
LYCHOPR	☐	☑	☐	*Dose modification section modified, Acetaminophen dose for infusion reactions revised*	Treatment of Lymphoma with Doxorubicin, Cyclophosphamide, Vincristine, Prednisone and Rituximab
LYCODOXMR	☑	☑	☐	*Acetaminophen dose for infusion reactions revised*	Treatment of Burkitt's Lymphoma and Leukemia (ALL-L3) with Cyclophosphamide, Vincristine, Doxorubicin, Methotrexate, Leucovorin (CODOX-M) and Rituximab
LYCVPR	☑	☑	☐	*Acetaminophen dose for infusion reactions revised*	Treatment of Advanced Indolent Lymphoma using Cyclophosphamide, Vincristine, Prednisone and Rituximab (CVP-R)
LYFLUDR	☑	☑	☐	*Acetaminophen dose for infusion reactions revised*	Treatment of Chronic Lymphocytic Leukemia or Prolymphocytic Leukemia with Fludarabine and Rituximab
LYIVACR	☑	☑	☐	*Acetaminophen dose for infusion reactions revised*	Treatment of Burkitt's Lymphoma and Leukemia (ALL-L3) with Ifosfamide, Mesna, Etoposide, Cytarabine (IVAC) and Rituximab
ULYRICE	☑	☑	☐	*Acetaminophen dose for infusion reactions revised*	Treatment of Advanced Stage Large B-Cell Non-Hodgkin's Lymphoma with Ifosfamide, Carboplatin, Etoposide and Rituximab
LYRITB	☑	☑	☐	*Acetaminophen dose for infusion reactions revised*	Palliative Therapy For Lymphoma Using Radioimmunotherapy: Tositumomab-Priming for I^{131} Tositumomab
LYRITUX	☑	☑	☐	*Acetaminophen dose for infusion reactions revised*	Treatment of Lymphoma with single agent Rituximab.
LYRITZ	☑	☑	☐	*Acetaminophen dose for infusion reactions revised*	Palliative Therapy For Lymphoma Using Radioimmunotherapy: Rituximab-Priming for Ibritumomab ^{90}Y
ULYRMTN	☑	☑	☐	*Acetaminophen dose for infusion reactions revised*	Maintenance Rituximab for Indolent Lymphoma
UMYLENDEX	☑	☑	☐	*Clarification of dose modifications, addition of prednisone option*	Therapy of Multiple Myeloma Using Lenalidomide with Dexamethasone

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, BC CANCER AGENCY 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, PRE-PRINTED ORDERS AND 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
COMPLEMENTARY AND ALTERNATIVE CANCER THERAPIES	under Patient/Public Info, Complementary Therapies

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	mlin@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
LIBRARY/CANCER INFORMATION	1-(888)-675-8001 Ext 8003	requests@bccancer.bc.ca
OSCAR HELP DESK	1-(888)-355-0355 Fax (604) 708-2051	oscar@bccancer.bc.ca
PHARMACY PROFESSIONAL PRACTICE	(250) 519.5574	jkippen@bccancer.bc.ca
ABBOTSFORD CENTRE (AC)	(604) 851-4710	Toll-free: 1-(877) 547-3777
CENTRE FOR THE SOUTHERN INTERIOR (CCSI)	(250) 712-3900	Toll-Free 1-(888) 563-7773
FRASER VALLEY CENTRE (FVCC)	(604) 930-2098	Toll-Free 1-(800) 523-2885
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