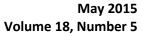
Systemic Therapy Update



BC Cancer Agency

ncy of the Provincial Health Services Authority

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 programs effective 1 May 2015:

Pomalidomide for Multiple Myeloma (UMYPOMDEX) – Pomalidomide with low dose dexamethasone will now be available for patients who are refractory or intolerant to bortezomib and lenalidomide. In one phase III trial comparing it to high dose dexamethasone, pomalidomide with low dose dexamethasone was associated with increased overall survival (12.7 vs. 8.1 mos, HR 0.74) and progression free survival (4.0 vs. 1.9 mos, HR 0.48) *[San Miguel. Lancet Oncol 2013;14(11):1055]* Worsening of fatigue and emotional function (feeling tense, worrying, irritable or depressed) were also delayed.

Common grade 3 toxicities associated with this new regimen include neutropenia, anemia, thrombocytopenia, pneumonia, bone pain and fatigue. Although neutropenia was more common than with high dose dexamethasone, there was no increase in the incidence of febrile neutropenia. Due to the risk of thromboembolic events, patients should be on prophylactic aspirin. Since pomalidomide is an analogue of thalidomide, similar precautions must be maintained to avoid potential teratogenic toxicity (see <u>www.RevAid.ca</u>). A BCCA Compassionate Access Program (CAP) approval is required for each patient.

EDITOR'S CHOICE

Note that patients who are currently on the manufacturer's Pomalyst Access Program will need to obtain CAP approval to have pomalidomide covered by BCCA.

Chemohormonal Therapy for Prostate Cancer (GUPDOCADT) – Androgen deprivation therapy (ADT) is the current standard therapy for patients with newly diagnosed, castration sensitive metastatic prostate cancer. ADT can be achieved medically with LHRH agonists or antagonist alone or with antiandrogens (total androgen blockade), or surgical castration. The new GUPDOCADT protocol will include addition of docetaxel chemotherapy to ADT based on results from a phase III trial *[Sweeney. ASCO 2014 abstract LBA2]*. Improved overall survival (49.2 vs 32.2 mos, HR 0.60) was shown in patients with high volume disease, defined as having visceral metastases or at least four bone metastases.

Doxorubicin for Endometrial and Uterine Malignancies (GOENDD, GOSAD) – These new palliative singleagent regimens are used for patients of good performance status and with advanced uterine sarcoma, epithelial endometrial cancer, malignant mixed Müllerian tumour or carcinosarcoma.

Vincristine, Dactinomycin and Cyclophosphamide for Rhabdomyosarcoma (SAVDC) – This regimen is similar to SAVDCM except that it does not contain mesna as a cytoprotection for the bladder. Therefore, it is indicated only in patients with no pelvic primaries and who would not receive radiotherapy to the bladder.

Cisplatin and Etoposide for Merkel Cell Carcinoma (SMMCCPE) – Merkel cell carcinoma is a rare, aggressive cutaneous tumour. This combination chemotherapy can offer disease control with potential survival benefit in patients with recurrent or metastatic disease.

NEW BCCA WEBSITE

This was launched on 21 April and it is best viewed on Google Chrome or Internet Explorer (version 8 or higher). To check what browser is on your computer, visit <u>http://whatbrowser.org/</u>

- The website homepage remains as <u>www.bccancer.bc.ca</u>.
- Information for health professionals is still in a section titled Health Professionals

 (www.bccancer.bc.ca/health-professionals). Key information for patients and families will be found in
 one of two sections: Our Services (www.bccancer.bc.ca/our-services) and Health Info
 (www.bccancer.bc.ca/health-info).
- Most sections have new URLs as the overall website structure has changed. Therefore, bookmarks and favourites will need to be updated. The new URLs for the most commonly used website resources are listed at the last page of this newsletter. For more details, see the April issue of the <u>Systemic Therapy</u> <u>Update (www.bccancer.bc.ca/health-professionals/professional-resources/systemic-therapy/systemic-therapy-update</u>).

More details about the new website are available at: <u>www.bccancer.bc.ca/about/news-stories/news/new-website-launched</u>.

CANCER DRUG MANUAL

New Drug

Pomalidomide monograph and patient handout have been developed with expert review provided by Dr. Kevin Song (Hematologist) and Linda Hamata (Pharmacist) from the BCCA Lymphoma Tumour Group.

Pomalidomide (POMALYST[®]) is an analogue of thalidomide. It is teratogenic and only available through a controlled distribution program called RevAid[®] (<u>www.RevAid.ca</u>). Physicians and pharmacists must register with the program to prescribe and dispense pomalidomide. Patients receiving pomalidomide must also register with RevAid[®] and be able to understand the conditions of the program (e.g., not sharing the medication, regular blood tests, aware of the common side effects).

Common side effects include myelosuppression, fatigue, infections, and dyspnea. There is also a risk for thromboembolic events and therefore prophylactic antithrombotic therapy (e.g., aspirin) may be recommended.

Etoposide Phosphate interim monograph has been developed to alert that it is not interchangeable with the regular etoposide formulation. Etoposide phosphate is only available via the Health Canada Special Access Programme. Although it has similar pharmacokinetics and dosing as the regular etoposide formulation, it does not contain polysorbate 80, an excipient which has been associated with the hypersensitivity reactions seen with the regular etoposide formulation.

HIGHLIGHTS OF REVISED MONOGRAPHS AND HANDOUTS

Vemurafenib: the monograph and patient handout have been revised in response to Health Canada alerts and post-marketing reports regarding:

- Development of non-cutaneous malignancies and accelerated progression of cancers related to RAS mutation
- Severe dermatologic drug reaction with eosinophilia and systemic symptoms (DRESS syndrome)
- Liver injury and pancreatitis
- Febrile neutropenia
- Panniculitis

Other changes

- Alemtuzumab: supplier and access information added under Supply and Storage
- **Pazopanib:** blood pressure monitoring and hypertension management added to patient information handout

BENEFIT DRUG LIST

New Programs

The following programs have been added to the <u>Benefit Drug List</u> effective 1 May 2015:

Protocol Title	Protocol Code	Benefit Status
Doxorubicin for use in patients with advanced endometrial cancer	GOENDD	Class I
Doxorubicin for use in patients with advanced uterine sarcoma	GOSAD	Class I
First-line treatment of castration sensitive, metastatic prostate cancer using docetaxel and androgen deprivation therapy (LHRH agonist [buserelin , goserelin , leuprolide] or LHRH antagonist [degarelix] with or without antiandrogen [bicalutamide , flutamide , nilutamide])	GUPDOCADT	Class I
Therapy of multiple myeloma using <i>pomalidomide</i> with <i>dexamethasone</i>	UMYPOMDEX	Restricted
Adjuvant therapy for rhabdomyosarcoma using <i>vincristine, dactinomycin</i> and <i>cyclophosphamide</i>	SAVDC	Class I
Treatment of recurrent or metastatic Merkel cell carcinoma with <i>cisplatin</i> and <i>etoposide</i>	SMMCCPE	Class I

REVISED PROGRAMS

The following program has been revised on the <u>Benefit Drug List</u> effective 1 May 2015:

Protocol Title	Protocol Code	Benefit Status
Neoadjuvant treatment of esophageal and gastroesophageal carcinomas using <i>carboplatin, paclitaxel</i> and radiation therapy	GIENACTRT	Class I (Previously Class II)

DELETED PROGRAMS

The following programs have been removed from the <u>Benefit Drug List</u> effective 1 May 2015:

Protocol Title	Protocol Code
Adjuvant therapy for breast cancer using cyclophosphamide, doxorubicin , fluorouracil and filgrastim	BRAJCAFG
Adjuvant therapy for breast cancer using oral cyclophosphamide , doxorubicin and fluorouracil	BRAJCAFPO
Therapy for inflammatory breast cancer using <i>cyclophosphamide, doxorubicin</i> and <i>fluorouracil</i>	BRINFCAF

COMMUNITIES ONCOLOGY NETWORK

REIMBURSEMENT FOR PURCHASES OF BACILLUS CALMETTE-GUÉRIN (BCG) ONCOTICE® VACCINE

As a result of the ongoing challenges with the HealthPRO contracted supplier for OncoTICE[®] vaccine:

- Health Authorities should submit any claims from 1 April 2015 onwards for OncoTICE[®] through the Online System for Cancer drugs Adjudication and Reimbursement (OSCAR) at the Merck acquisition price and not the Hospira contract price.
- Health Authorities will need to submit to HealthPRO by **31 July 2015** for any cost differentials between the acquisition price and contract price for purchases from 1 January through 31 May 2015.
- BCCA will reimburse the remaining cost differentials not covered by Hospira and the OSCAR claims submissions invoiced from 1 January 2014 through 31 May 2015. To facilitate this payment, BCCA will need the actual BCG inventory on hand as of end of day of **31 May 2015**. An email reminder will be sent out to the Health Authorities' purchasers closer to the date.

For more information, please contact OSCAR at <u>oscar@bccancer.bc.ca</u> or 1-888-355-0355.

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 BCCA Compassionate Access Program approval are prefixed with the letter "U".

NEW PROTOCOLS, PPPOS AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED):					
CODE	Protocol	РРРО	Patient Handout	Protocol Title	
GOENDD	V	\checkmark		Doxorubicin for Use in Patients with Advanced Endometrial Cancer	
GOSAD	\checkmark	\checkmark		Doxorubicin for Use in Patients with Advanced Uterine Sarcoma	
GUPDOCADT	V	\checkmark		First-Line Treatment of Castration Sensitive, Metastatic Prostate Cancer Using DOCEtaxel and Androgen Deprivation Therapy	
ULUAVAFAT			V	First-Line Treatment of Epidermal Growth Factor Receptor Mutation- Positive Advanced Non-Small Cell Lung Cancer with Afatinib	
UMYPOMDEX	V	\checkmark		Therapy of Multiple Myeloma Using Pomalidomide with Dexamethasone	
SAVDC	V	\checkmark		Adjuvant Therapy for Rhabdomyosarcoma Using vinCRIStine, Dactinomycin, and Cyclophosphamide	
SMMCCPE	\checkmark	\checkmark		Treatment of Recurrent or Metastatic Merkel Cell Carcinoma with CISplatin and Etoposide	

REVISED PROTOCOLS, PPPOS AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED):						
CODE	Protocol	РРРО	Patient Handout	Changes	Protocol Title	
BRAJACTW	V	V		Paclitaxel infusion volume clarified	Adjuvant Therapy for Early Breast Cancer Using DOXOrubicin and Cyclophosphamide followed by Weekly PACLitaxel	
BRLATWAC	V	V		Eligibility and paclitaxel infusion volume clarified	NeoAdjuvant Therapy for Locally Advanced Breast Cancer Using Weekly PACLitaxel Followed by DOXOrubicin and Cyclophosphamide	
GICART	V	\checkmark		Mitomycin dose clarified	Curative Combined Modality Therapy for Carcinoma of the Anal Canal Using Mitomycin, Capecitabine and Radiation Therapy	
GIENACTRT	V	\checkmark		Benefit status changed to class I	Neoadjuvant Treatment of Esophageal and Gastroesophageal Carcinomas Using CARBOplatin, PACLitaxel and Radiation Therapy	
GIFUART	V	\checkmark		Mitomycin dose clarified, INR monitoring added	Curative Combined Modality Therapy for Carcinoma of the Anal Canal Using Mitomycin, Infusional Fluorouracil and Radiation Therapy	
GOOVDDCAT	V	\checkmark		Paclitaxel infusion volume clarified	Treatment of Advanced Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Carcinoma Using CARBOplatin and Weekly PACLitaxel	
GOOVDOC	V			Treatment duration revised	Treatment Of Progressive, Platinum- Refractory Epithelial Ovarian Carcinoma, Primary Peritoneal Carcinoma or Fallopian Tube Carcinoma Using DOCEtaxel	
GOOVLDOX	V			Treatment duration revised	Treatment of Relapsed/Progressing, Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Carcinoma Using Pegylated Liposomal DOXOrubicin	
HNNAVPG			V	Gemcitabine dosing schedule clarified	Treatment of Locoregionally Recurrent or Metastatic Nasopharyngeal Cancer with Platinum and Gemcitabine	
LUAVERL	V			Minocycline for rash management added	Second- or Third-Line Treatment of Advanced Non-Small Cell Lung Cancer with Erlotinib	
ULUAVGEFF	V			Minocycline for rash management added	First-Line Treatment of Epidermal Growth Factor Receptor Mutation- Positive Advanced Non-Small Cell Lung Cancer with Gefitinib	
ULUAVMTNE	V			Minocycline for rash management added	Maintenance Therapy of Advanced Non- Small Cell Lung Cancer with Erlotinib After First-Line Chemotherapy	
ULKMDSA		\checkmark		Lab tests clarified	Therapy of Myelodysplastic Syndrome Using Azacitidine	
ULYCLLBEND	V			Eligibility clarified	Treatment of Relapsed Chronic Lymphocytic Leukemia with Bendamustine	
SAAJAP			V	Treatment summary clarified	Adjuvant Treatment of Osteosarcoma with Doxorubicin and Cisplatin	
USAAVGR		\checkmark		Timing of lab tests clarified	Third Line Therapy of Advanced Gastrointestinal Stromal Cell Tumours Using Regorafenib	

Using Regorafenib

REVISED PROTOCOLS, PPPOS AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED):					
CODE	Protocol	РРРО	Patient Handout	Changes	Protocol Title
USMAVDAB	V	\checkmark		Lab tests revised	Treatment of BRAF V600 Mutation- Positive Unresectable or Metastatic Melanoma Using Dabrafenib
USMAVVEM	\checkmark	\checkmark		Lab tests revised	Treatment of BRAF V600 Mutation- Positive Unresectable or Metastatic Melanoma Using Vemurafenib

DELETED Protocols, PPPOs and Patient Handouts (AFFECTED DOCUMENTS ARE CHECKED):					
CODE	Protocol	PPPO	Patient Handout	Protocol Title	
BRAJCAFG	\checkmark	\checkmark		Adjuvant Therapy for Breast Cancer Using Cyclophosphamide, DOXOrubicin , Fluorouracil and Filgrastim	
BRAJCAFPO	\checkmark	\checkmark	\checkmark	Adjuvant Therapy for Breast Cancer Using Oral Cyclophosphamide, DOXOrubicin and Fluorouracil	
BRINFCAF	\checkmark	\checkmark		Therapy for Inflammatory Breast Cancer Using Cyclophosphamide, DOXOrubicin and Fluorouracil	

WEBSITE RESOURCES AND CONTACT INFORMATION

WEBSITE RESOURCES	www.bccancer.bc.ca
Systemic Therapy Update	www.bccancer.bc.ca/health-professionals/professional-resources/systemic-therapy/systemic- therapy-update
Reimbursement & Forms: Benefit Drug List, Class II, Compassionate Access Program	www.bccancer.bc.ca/health-professionals/professional-resources/systemic-therapy
Cancer Drug Manual	www.bccancer.bc.ca/health-professionals/professional-resources/cancer-drug-manual
Cancer Management Guidelines	www.bccancer.bc.ca/health-professionals/professional-resources/cancer-management- guidelines
Cancer Chemotherapy Protocols, Pre-printed Orders, Protocol Patient Handouts	www.bccancer.bc.ca/health-professionals/professional-resources/chemotherapy-protocols
Systemic Therapy Program Policies	www.bccancer.bc.ca/health-professionals/professional-resources/systemic-therapy
CON Pharmacy Educators	www.bccancer.bc.ca/health-professionals/professional-resources/pharmacy

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Library/Cancer Information	604.675.8003 Toll Free 888.675.8001 x 8003		requests@bccancer.bc.ca
Pharmacy Professional Practice	604.877.6000 x 672247		mlin@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 250.645.7300		
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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