Systemic Therapy Update



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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 December 2014:

Dabrafenib for BRAF Mutation Positive Unresectable or Metastatic Melanoma (USMAVDAB) -

Dabrafenib is an oral BRAF kinase inhibitor selective for tumour cells expressing mutated BRAF V600 proteins. Approximately 40-60% of metastatic melanomas carry this mutation. In phase III trial involving 250 treatment-naïve patients with BRAF V600 mutation-positive metastatic unresectable or metastatic melanoma, dabrafenib was associated with increased progression free survival (PFS) (6.7 vs. 2.9 mos, HR 0.35) and response rate (52% vs. 17%) compared to Dacarbazine. [Hauschild et al. Lancet 2012] Indirect comparison suggests that dabrafenib may have a lower incidence of phototoxicity and new primary malignancies than vemurafenib, which is currently funded by BCCA in this setting. However, higher rates of palmar-plantar erthyrodysesthesia, pyrexia and hyperglycemia have been reported for dabrafenib. Of note, the BCCA will only approve up to one anti-BRAF therapy (vemurefenib or dabrafenib) for this indication.

EDITOR'S CHOICE

Radium-223 (XOFIGO®) for Castration Resistant Metastatic Prostate (UGUPRAD) — Current therapeutic options for this patient population include hormonal therapy (abiraterone, enzalutamide) and chemotherapy (docetaxel). For patients who have failed or are not otherwise eligible for these systemic therapies, radium-223 may palliate symptomatic bone metastases. In a phase III trial, radium-223 was associated with increased overall survival (14 vs. 11 months) and delayed time to first skeletal related event (13.6 vs. 8.4 months) compared to placebo [Nilsson S, et al. Lancet Oncol 2007;8:587]. Therapy with radium-223 was well tolerated, with a lower rate of overall and serious adverse events than the placebo group. A BCCA Compassionate Access Program application is required for each patient.

Temozolomide for Elderly Patients with Glioblastoma Multiforme (GBM) with MGMT Promoter Methylation (CNTEMM) — Current standards of chemoradiotherapy are not always well tolerated in older patients with GBM, particularly in those over age 70, whereby there is no supporting data that combined chemoradiotherapy is more effective than less intensive therapies. In one phase III trail involving 412 patients over the age of 65, temozolomide was shown to be non-inferior to radiation alone in overall survival (9.6 s. 8.6 mos) and even-free survival (4.7 vs. 3.3 mos). [Wick et al. Lancet 2012;13:707] In the subgroup of 75 patients with MGMT promoter methylation, temozolomide was associated with longer event-free survival (8.4 vs. 4.6 mos) and a trend of longer overall survival.

REVISED PROGRAMS

The Provincial Systemic Therapy Program has revised the following program effective 1 December 2014:

Trastuzumab Emtansine (KADCYLA®) for HER2 Positive Metastatic Breast Cancer (UBRAVKAD) – The eligibility has been revised to include patients who were started or had completed at least two lines of anti-HER2 therapy prior to the BCCA implementation of the UBRAVKAD protocol on 1 May 2014. This means that current patients who have progressed during or after previous HER2-targeted therapy prior to 1 May 2014, but who have not received trastuzumab emtansine (KADCYLA®) will also be eligible regardless of the number of lines of therapy that patient has had for metastatic breast cancer.

Modified PCV for Brain Tumours (CNMODPCV) – The eligibility has been revised to include patients with incompletely resected low grade gliomas as well as patients over age 40 and with completely resected low grade gliomas. The chemotherapy regimen should start two weeks after radiotherapy. In a recent phase III study, addition of PCV chemotherapy after radiation was associated with increased overall survival (13.3 vs. 7.8 yrs, HR = 0.59) and progression free survival (10.4 vs. 4.0 yrs, HR = 0.50). [Buckner JC et al. J Clin Oncol 2014;32:5s (abstr 2000)]

HIGHLIGHTS OF CHANGES IN PROTOCOLS, PPPOS AND PATIENT HANDOUTS

Capecitabine-Based Gastrointestinal Protocols and PPPOs – These have been revised to clarify the need and frequency of INR monitoring in patients who are on concurrent warfarin (see Medication Safety Corner in this issue).

Weekly Paclitaxel Therapy for Metastatic Breast Cancer – The current protocol BRAVT7 for weekly paclitaxel is being replaced with a new protocol BRAVTW. The new regimen is based on the results of the E2100 study [Miller K et al. N Engl J Med 2007;357:2666] and the CALGB 40502 Study [Rugo HS et al. J Clin Oncol 2012;30:CRA1002]. It has a slightly higher dose at 90 mg/m² and is given every 3 weeks out of 4 weeks, thus

HIGHLIGHTS OF CHANGES IN PROTOCOLS, PPPOS AND PATIENT HANDOUTS

reducing the number of visits for treatment.

During the transition period from BRAVT7 to BRAVTW, heightened awareness regarding the dose and frequency of treatment will be required. Existing patients should complete their current cycle of treatment on BRAVT7, then switch to BRAVTW at the start of their next cycle.

Translated Protocol Patient Handouts – Chinese and Punjabi translations are now available for a number of Protocol Patient Handouts (see affected handouts in the table <u>below</u>). This is part of an ongoing BCCA pilot project to address the needs of non-English speaking patients throughout the province.

"Save the date: Dilution of all Vinca Alkaloids in Minibag Effective 1 February 2015" – Vinca alkaloids, when given *inadvertently* by intrathecal route, can result in death. While most reported incidents related to vinCRIStine, fatalities have occurred due to vinBLAStine as well.¹⁻³ In the 2014-2015 targeted best practices for medication safety in hospitals, the US Institute for Safe Medication Practices (ISMP) recommends that all vinca alkaloids be dispensed in minibags.⁴

Currently, vinCRIStine and vinorelbine are dispensed in minibags at BCCA. Effective 1 February 2015, this practice will expand to include ALL vinca alkaloids. Corresponding changes will be updated in the protocols, PPPOs, monographs and chemotherapy preparation and stability chart of the Cancer Drug Manual. The affected protocols are all vinBLAStine-based regimens:

GUBCV LYABVD
GUMVAC LYCVPPABO
BUVEIP SAMV

KSVB

References

- World Health Organization. Information Exchange System: Alert No. 115 (QSM/MC/IEA.115). Geneva, Switzerland: World Health
 Organization; 2007 Jul 18 [cited 2014 Jul 14]. 2p. Available from: www.who.int/medicines/publications/drugalerts/Alert_115_vincristine.pdf
- Death and neurological devastation from intrathecal vinca alkaloids:
 Prepared in syringes = 120; Prepared in minibags = 0. ISMP Medication Safety Alert Acute Care [Internet]. 2013 Sep 5 [cited 2014 Jul 14].
 Available from: www.ismp.org/Newsletters/acutecare/showarticle.aspx?id=58

MEDICATION SAFETY CORNER

MONITORING INR OF PATIENTS ON CONCURRENT CAPECITABINE AND WARFARIN

Patient Safety Learning Summary – Patient had been taking warfarin prior to commencing capecitabine and did not have INR monitored as frequently as needed. This led to a serious complication.

What were the contributing factors / systems issues identified?

- No standardization of warfarin management, INR frequency monitoring or checkboxes for protocol.
- Language in patient handout does not indicate the requirement to have INR if diarrhea occurs while taking capecitabine and warfarin.
- Failure to order INR blood test when patient developed diarrhea.
- No communication to GP by MRP when patient developed diarrhea.
- Healthcare providers did not recognize potential concern of patient having severe diarrhea while taking warfarin and capecitabine.
- Irregular monitoring of INR by GP.

MEDICATION SAFETY CORNER

What actions were taken?

- Review all pre-printed orders with capecitabine to standardize management of patients on warfarin during and post chemotherapy treatment.
- Review and revise symptom management guidelines for diarrhea to ensure that the management of patients on warfarin is included.
- Review pharmacy standard work to ensure that the patient is informed regarding the need for more frequent INR blood tests while on capecitabine.

This report has been prepared at the direction of the Quality Council/ Patient Safety Committee. The information may be privileged under section 51 of the British Columbia Evidence Act. It has been abstracted from an actual critical incident review, but identifying information has been removed or modified in order to circulate to health care providers and organizations to promote learning from critical incidents.

DRUG UPDATE

SHORTAGE OF MITOMYCIN

A temporary shortage of drug supply is expected until March 2015. Mitomycin is used with concurrent radiotherapy in two combined modality protocols for anal cancer with curative intent (GIFUART, GICART). It is also an alternative intravesical agent to Bacillus Calmette-Guérin (BCG) vaccine for superficial transitional cell bladder cancer (GUBMITO). Potential alternative chemotherapy agents for anal cancer are being reviewed. For alternative intravesical agents for bladder cancer, see the October issue of the Systemic Therapy Update.

CANCER DRUG MANUAL

NEW MONOGRAPHS AND PATIENT HANDOUTS

Afatinib Monograph and Patient Handout have been developed with expert review provided by Dr. Chris Lee (Medical Oncologist, BCCA Lung Tumour Group) and Alysha Bharmal (Pharmacist, BCCA Lung Tumour Group). Afatinib is a second generation, irreversible tyrosine kinase inhibitor indicated for the first line treatment of EGFR mutation-positive advanced non-small cell lung cancer (BCCA Protocol ULUAVAFAT). Afatinib is taken orally, on an empty stomach (either one hour before or three hours after food). Common side effects of afatinib include diarrhea, paronychia, and skin reactions such as rash, pruritus and dermatitis acneiform. Onset of diarrhea usually occurs with the first 2 weeks of treatment; close monitoring and early intervention is essential to prevent the development of more severe diarrhea. Early intervention is also beneficial for the management of skin related adverse events. Exposure to sun may aggravate skin reactions; therefore, patients should be counselled to wear sun protection during treatment.

Dabrafenib Monograph and **Patient Handout** have been developed. Dabrafenib is an oral, small molecule inhibitor of BRAF serine-threonine kinase, selective to BRAF-V600 mutations. Similar to other BRAF inhibitors (e.g. vemurafenib), it is used for the treatment of BRAF V600 mutation-positive unresectable or metastatic melanoma (BCCA Protocol USMAVDAB). Dabrafenib should not be used in patients with wild-type BRAF melanoma. Compared to vemurafenib, dabrafenib has a higher incidence of pyrexia, palmar-plantar erthyrodysesthesia syndrome, and hyperglycemia, but is associated with less photosensitivity,

CANCER DRUG MANUAL

arthralgia and fatigue. New primary melanomas and secondary malignancies, including cutaneous squamous cell carcinoma and non-cutaneous malignancies, have been reported with dabrafenib.

REVISED MONOGRAPHS, PATIENT HANDOUTS AND HAZARDOUS DRUG LIST

Bleomycin Monograph:

• Side Effects – acute arthritis has been deleted as it is no longer included in standard references and there have been no cases in the published literature.

Nab-Paclitaxel Monograph:

■ Solution Preparation — filtration instructions have been added for the rare occurrence of proteinaceous strands in the final compounded product

Sorafenib Monograph:

 Side Effects – osteonecrosis of the jaw has been added based on rare reports in postmarketing surveillance.

CONTINUING PROFESSIONAL DEVELOPMENT

ELEARNING SUPPORT FOR ONCOLOGY NURSING CERTIFICATION 2015

Have you been thinking of formally recognizing your oncology nursing knowledge through specialty certification? The Canadian Nurses Association (CNA) certification is the only nationally recognized specialty certification in Canada. Certification exams occur annually in 20 specialty areas of nursing practice – Oncology being one of these areas.

If you have applied to write the Oncology Certification Exam on 18 April 2015, then you are invited to participate in a virtual study group via the PHSA Learning Hub starting in January 2015. Some of the advantages of specialty certification include formal recognition in the workplace and university credit towards your nursing degree. More information on eligibility criteria and how to apply can be found at: CNA certification (https://nurseone.ca/en/certification)

BENEFIT DRUG LIST

New Programs

The following programs have been added to the Benefit Drug List effective 1 December 2014:

Protocol Title	Protocol Code	Benefit Status
Therapy for Newly Diagnosed Malignant Brain Tumours with MGMT Methylation in Elderly Patients using Temozolomide	CNTEM60	Class II
Therapy for Metastatic Castration Resistant Prostate Cancer Using Radium-223	UGUPRAD	Restricted

BENEFIT DRUG LIST		
Treatment of BRAF V600 Mutation-Positive Unresectable or Metastatic Melanoma Using Dabrafenib	USMAVDAB	Restricted
	•	

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".

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

CODE	Protocol	PPPO	Patient Handout	Protocol Title		
BRAVTW	V	V		Palliative Therapy for Metastatic Breast Cancer using Weekly PACLitaxel (3 Weeks Out of 4 Weeks Schedule)		
CNTEM60	V	V		Therapy for Newly Diagnosed Malignant Brain Tumours with MGMT Methylation in Elderly Patients using Temozolomide		
UGUPRAD	V			Therapy for Metastatic Castra Radium-223	ntion Resistant Prostate Cancer Using	
USMAVDAB				Treatment of BRAF V600 Mutation-Positive Unresectable or Metastatic Melanoma Using Dabrafenib		
REVISED PROTOC	ois. PPPOs 4	AND PATIENT I	HANDOUTS (A	FFECTED DOCUMENTS ARE CHECKE	:n)·	
CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title	
BRAJACT	\square			Eligibility clarified	Adjuvant Therapy for Breast Cancer using DOXOrubicin and Cyclophosphamide followed by PACLitaxel	
BRAJACTW	V			Eligibility clarified	Adjuvant therapy for Early Breast Cancer Using DOXOrubicin and Cyclophosphamide Followed by Weekly PACLitaxel	
UBRAJDAC	V			Eligibility clarified	Adjuvant Therapy for Breast Cancer using Cyclophosphamide, DOXOrubicin and DOCEtaxel	
BRAJFECD	V			Eligibility clarified	Adjuvant Therapy for Breast Cancer Using Fluorouracil, Epirubicin and Cyclophosphamide and DOCEtaxel	
BRAJFECDT	Ø			Eligibility clarified	Adjuvant Therapy for Breast Cancer Using Fluorouracil, Epirubicin and Cyclophosphamide Followed by DOCEtaxel and Trastuzumab (HERCEPTIN)	
UBRAVKAD	V			Eligibility updated	Palliative Therapy for Metastatic Breast Cancer Using Trastuzumab Emtansine	

REVISED Protocols, PPPOs and Patient Handouts (Affected Documents are Checked):						
CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title	
CNMODPCV	V	Ø		Eligibility, treatment and dose modifications information updated for low grade gliomas	Modified PCV Chemotherapy Of Brain Tumours Using Procarbazine, Lomustine and vinCRIStine	
GIAJCAP	V			Warfarin monitoring updated	Adjuvant Therapy of Colon Cancer using Capecitabine	
GIAJCAPOX	V			Warfarin monitoring updated	Adjuvant Combination Chemotherapy for Stage III and Stage IIB Colon Cancer Using Oxaliplatin and Capecitabine	
GIAVCAP	$\overline{\mathbf{A}}$	\square		Warfarin monitoring updated	Palliative Therapy of Advanced Colorectal Cancer using Capecitabine	
GIAVTZCAP	V	V		Warfarin monitoring updated	Palliative Therapy of Metastatic Neuroendocrine Cancer Using Temozolomide and Capecitabine	
GICAPIRI	$\overline{\mathbf{A}}$			Warfarin monitoring updated	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Irinotecan and Capecitabine in Patients Unsuitable for GIFOLFIRI	
GICAPOX	Ø			Warfarin monitoring updated	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Oxaliplatin, and Capecitabine	
GICART	V			Warfarin monitoring updated	Curative Combined Modality Therapy for Carcinoma of the Anal Canal using mitoMYcin, Capecitabine and Radiation Therapy	
GICIRB	V			Warfarin monitoring updated	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Irinotecan, Bevacizumab and Capecitabine	
UGICOXB	V			Warfarin monitoring updated	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Oxaliplatin, Bevacizumab and Capecitabine	
GICPART	V			Warfarin monitoring updated	Curative Combined Modality Therapy for Carcinoma of the Anal Canal using CISplatin, Capecitabine and Radiation Therapy	
GIGAJCC	V	Ø		Warfarin monitoring updated	Adjuvant Chemotherapy of Gastric Cancer patients with D2 Resection (node negative) or ineligible for adjuvant chemoradiation, using CISplatin and Capecitabine	
GIGAJCPRT	V			Warfarin monitoring updated	Adjuvant Chemotherapy of Gastric Cancer patients with Completely Resected Gastric Cancer using CISplatin and Capecitabine and Radiation Therapy	
GIGAVCC	V	V		Warfarin monitoring updated	Palliative Therapy for Metastatic or Locally Advanced Gastric Cancer using CISplatin and Capecitabine	
GIGAVCCT	V	4		Warfarin monitoring updated	Palliative Treatment of Metastatic or Inoperable, Locally Advanced Gastric or Gastroesophageal Junction Adenocarcinoma Using CISplatin, Capecitabine and Trastuzumab (HERCEPTIN)	

REVISED PROTOCOLS, PPPOS AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED):						
CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title	
GIGAVECC				Warfarin monitoring updated	Palliative Therapy for Metastatic or Locally Advanced Gastric or Esophagogastric Cancer Using Epirubicin, CISplatin and Capecitabine	
GIGECC	V			Warfarin monitoring updated	Perioperative Treatment of Resectable Adenocarcinoma of the Stomach, Gastroesophageal Junction or Lower 1/3 Esophagus using Epirubicin, CISplatin and Capecitabine	
GIGECF		Ø		Return appointment section clarified	Perioperative Treatment of Resectable Adenocarcinoma of the Stomach, Gastroesophageal Junction or Lower 1/3 Esophagus using Epirubicin, CISplatin and Infusional Fluorouracil	
UGIPGEMABR				Eligibility clarified	First Line Treatment of Locally Advanced and Metastatic Pancreatic Cancer with PACLitaxel-Nab (ABRAXANE®) and Gemcitabine	
GIRAJCOX	\square			Warfarin monitoring updated	Adjuvant Combination Chemotherapy for Stage III Rectal Cancer Using Oxaliplatin and Capecitabine	
GIRCAP				Warfarin monitoring updated	Adjuvant Therapy for Stage II and III Rectal Cancer Previously Treated with Preoperative Radiation Therapy using Capecitabine	
GIRCRT	$\overline{\checkmark}$	V		Warfarin monitoring updated Combined Modality Adjuvant T for High Risk Rectal Carcinoma Capecitabine and Radiation The		
GIRINFRT				Warfarin monitoring updated	Combined Modality Adjuvant Therapy for High Risk Rectal Carcinoma using Capecitabine, Infusional Fluorouracil and Radiation Therapy	
LUAVPEM		$\overline{\checkmark}$		Hypersensitivity precaution clarified Second-Line Treatment of Advance Non-Small Cell Lung Cancer With Pemetrexed		
ULUAVPMTN		$\overline{\checkmark}$		Hypersensitivity precaution clarified	Maintenance Therapy of Advanced Non- Small Cell Lung Cancer With Pemetrexed	

NEW Translated Protocol Patient Handouts (Chinese and Punjabi):				
CODE	Protocol Title			
GUBPWRT	Treatment of Locally Advanced Bladder Cancer with Weekly CISplatin and Concurrent Radiation			
GUSCPERT	Therapy of Genitourinary Small Cell Tumors with a Platin and Etoposide with Radiation			
HNLAPRT	Combined Chemotherapy (CISplatin) and Radiation Treatment for Locally Advanced Squamous Cell Carcinoma of The Head and Neck			
HNNLAPRT	Treatment of Locally Advanced Nasopharyngeal Cancer with Concurrent CISplatin and Radiation			

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