Systemic Therapy Update



October 2012 Volume 15, Number 10 Supplement 1

For Health Professionals Who Care For Cancer Patients

Inside This Issue:

- New Programs Vemurafenib for BRAF Mutation-Positive Unresectable or Metastatic Melanoma
- Cancer Drug Manual <u>New</u>: Vemurafenib (Interim)
- Benefit Drug List New: Vemurafenib for BRAF V600 Mutation-Positive Unresectable or Metastatic Melanoma
- List of New and Revised Protocols, Pre-Printed Orders and Patient Handouts – New: USMAVVEM
- Website Resources and Contact Information

New Programs

The Provincial Systemic Therapy Program has approved the following new program effective immediately:

Melanoma:

Vemurafenib for the Treatment of BRAF V600 Mutation-Positive Unresectable or Metastatic Melanoma (USMAVVEM) – Vemurafenib is an oral BRAF kinase inhibitor selective for tumour cells expressing mutated BRAF V600 proteins. Approximately 40% to 60% of metastatic melanomas carry this mutation. In the landmark BRIM-3 trial involving 675 treatment-naïve patients with BRAF V600 mutation-positive metastatic melanoma, vemurafenib was associated with a 20% overall survival advantage at 6 months compared to dacarbazine, a historical treatment standard (84% vs. 64%). [Chapman et al. N Engl J Med 2011; 364:2507-2516] In a phase II trial (BRIM-2) involving 132 previously treated, BRAF V600 mutation-positive metastatic melanoma patients, vemurafenib demonstrated an overall response rate of 53% and a median progression free survival of 6.8 months. [Sosman et al. N Engl J Med 2012; 366:707-14]

Vemurafenib received the Health Canada Notice of Compliance in February 2012, and eligible patients were granted access to the drug through the Roche Patient Assistance Program (RPAP) (see <u>June 2012</u> issue of the Systemic Therapy Update). Patients who were enrolled in RPAP on or prior to 15 August 2012 would continue to access vemurafenib via RPAP. After 15 August 2012, all eligible BCCA patients must seek approval from the BCCA Compassionate Access Program for vemurafenib access. Because BRAF testing is not currently offered at the BCCA, RPAP will continue to coordinate BRAF gene testing until 31 December 2012. To inquire about BRAF testing services via RPAP, please call 1-888-748-8926. This information has been updated on the <u>BCCA Patient Assistance Programs</u> website. For more information on vemurafenib, please see the <u>Cancer Drug Manual</u> section of the current Update supplement.

CANCER DRUG MANUAL

NEW MONOGRAPHS AND PATIENT HANDOUTS

Vemurafenib Interim Monograph, Patient Handout, and **Hazardous Drug Evaluation** have been completed. Vemurafenib is indicated for the treatment of BRAF V600 mutation-positive, unresectable or metastatic melanoma at a recommended dose of 960 mg orally twice daily. QTc-prolongation has been observed with vemurafenib. Concurrent therapy with other QTc-prolonging drugs may increase the risk of potentially fatal arrhythmias and should be avoided if possible. Please see the New Programs section of the current Update supplement for further treatment details.

BENEFIT DRUG LIST

New Programs

The following program has been added to the Benefit Drug List effective immediately:

 Vemurafenib (restricted) for treatment of BRAF V600 mutation-positive unresectable or metastatic melanoma (USMAVVEM)

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			
USMAVVEM	$\overline{\checkmark}$	$\overline{\checkmark}$		Treatment of BRAF V600 Mutation-Positive Unresectable or Metastatic Melanoma Using Vemurafenib			

Website Resources and Contact Information						
WEBSITE RESOURCES	www.bccancer.bc.ca					
Reimbursement & Forms: Benefit Drug List, Class II, Compassionate Access Program	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, 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					
CON Pharmacy Educators	http://www.bccancer.bc.ca/HPI/Pharmacy/ContactUs.htm					

CONTACT INFORMATION	PHONE	FAX	EMAIL
Systemic Therapy Update Editor	604.877.6000 x 3028		sman3@bccancer.bc.ca
Provincial Systemic Therapy Program	604.877.707.5973		ldasilva2@bccancer.bc.ca
Communities Oncology Network (CON)	250.519.5501		jdenduyf@bccancer.bc.ca
Oncology Drug Information	604.877.6275		druginfo@bccancer.bc.ca
Education Resource Nurse	604.877.6000 x 2638		nursinged@bccancer.bc.ca
Library/Cancer Information	888.675.8001 x 8003		requests@bccancer.bc.ca
Pharmacy Professional Practice	250. 519.5574		jkippen@bccancer.bc.ca
Nursing Professional Practice	604.877.6000 x 2623		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		
BCCA-Sindi Ahluwalia Hawkins Centre for the	250.712.3900		
Southern Interior	Toll Free 888.563.7773		
BCCA-Fraser Valley Centre	604.930.2098		
,	Toll Free 800.523.2885		
BCCA-Vancouver Centre	604.877.6000 Toll Free 800.663.3333		
	250.519.5500		
BCCA-Vancouver Island Centre	Toll Free 800.670.3322		

EDITORIAL REVIEW BOARD

Sally Man, PharmD (Editor) Mário de Lemos, PharmD, MSc (Oncol) Johanna Den Duyf, MA Caroline Lohrisch, MD Beth Morrison, MLS Lindsay Schwartz, RN, MScA Jaya Venkatesh, MHA, CMA Susan Walisser, BSc (Pharm)