Systemic Therapy Update

BC Cancer Agency
CARE + RESEARCH
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For Health Professionals Who Care For Cancer Patients

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EDITOR'S CHOICE

NEW PROGRAMS

Effective 1 March 2017, the BCCA Provincial Systemic Therapy Program has approved the following three nivolumab programs. Access to these programs will require a BCCA Compassionate Access Program approval. Nivolumab is a new immunotherapy checkpoint inhibitor. More information about this agent can be found in the Cancer Drug Manual section in this issue. Management of the associated toxicities is detailed in the appendices of the treatment protocols, as well as the Nursing Immunotherapy Toolkit on the BCCA Nursing website.

Genitourinary:

Nivolumab for Advanced Renal Cell Carcinoma (UGUAVNIV) After At Least One Prior Line of Therapy – Everolimus or axitinib were the previous standard second-line therapies after failure of a first-line tyrosine kinase inhibitor (sunitinib or pazopanib) in patients with advanced renal cell carcinoma (RCC). Nivolumab is now approved as the standard second-line therapy after failure of first-line sunitinib or pazopanib, and the standard third-line therapy after failure of second-line axitinib. Please note that eligible patients may receive nivolumab or everolimus for this indication, but not the sequential use of these agents, with the exception of patients who have had everolimus prior to 1 March 2017.

In the phase III CheckMate 025 trial involving 821 patients treated with one or two prior lines of therapy, nivolumab demonstrated superior median overall survival (25.0 mo vs. 19.6 mo [HR 0.73, 95% CI 0.57-

0.93]) when compared to everolimus.[1] This is the first randomized controlled trial to demonstrate an overall survival benefit in this patient population. Nivolumab was associated with improved quality of life and lower rates of grades 3 and 4 toxicities. For further information about the toxicities and pharmacology of nivolumab, please see the Cancer Drug Manual section below.

Lung:

Nivolumab for Advanced Non-Small Cell Lung Cancer (NSCLC) After Failure of Chemotherapy (ULUAVNIV) – Nivolumab is now available for eligible patients through the BCCA Compassionate Access Program. Approval of this program is based on two phase III trials (CheckMate 017, CheckMate 057) that compared nivolumab with docetaxel (a standard second-line treatment) in patients whose disease progressed after first-line chemotherapy.[2-3] The median overall survival benefit for nivolumab was around 3 months in both trials, with a hazard ratio ranging from 0.59 to 0.73. The trials also demonstrated much lower rates of grades 3 and 4 toxicities as well as a delay in deterioration of quality of life with nivolumab. For further information about the toxicities and pharmacology of nivolumab, please see the Cancer Drug Manual section below. Please note that eligible patients may receive nivolumab or pembrolizumab for this indication, but not the sequential use of these agents.

Of note, the CheckMate 057 trial enrolled 582 patients with non-squamous advanced NSCLC of which 22% did not have quantifiable PD-L1 expression.[3] This small subset of patients did not demonstrate a clear benefit with nivolumab compared to docetaxel. Hence, while testing of PD-L1 expression is not required to access nivolumab at the BCCA, it may be helpful to guide therapy in patients with non-squamous histology.

Skin & Melanoma:

Nivolumab for Previously Untreated BRAF Wild-Type Metastatic Melanoma (USMAVNIV) – Approval of this new treatment program was based on the phase III CheckMate 067 trial, where nivolumab demonstrated superior overall response rates (43.7% vs. 19.0%, OR 6.11 [HR 95% CI 3.59-10.38] and median progression-free survival (6.9 mo vs. 2.9 mo, HR 0.57 [99.5% CI 0.43-0.76]) compared to ipilimumab, a standard first-line therapy.[4] Subgroup analysis showed that only patients with BRAF wild-type disease demonstrated this survival benefit, but not patients who were BRAF V600 mutation-positive. Overall, nivolumab was better tolerated than ipilimumab, and was associated with lower rates of grades 3 and 4 toxicities (16.3% vs. 27.3%) and lower discontinuation rates due to treatment-related adverse effects (7.7% vs. 14.8%). For further information about the toxicities and pharmacology of nivolumab, please see the Cancer Drug Manual section below. Please note that eligible patients may receive nivolumab, pembrolizumab or ipilimumab for this indication, but not the sequential use of these agents.

References:
1. Motzer RJ, Escudier B, McDermott DF, et al. Nivolumab versus everolimus in advanced renal-cell carcinoma. NEJM 2015;373;1803-1813.
2. Brahmer J, Reckamp KL, Baas P, et al. Nivolumab versus docetaxel in advanced squamous-cell non-small-cell lung cancer. NEJM 2015;373:123-135.
3. Borghaei H, Paz-Ares L, Horn L, et al. Nivolumab versus docetaxel in advanced nonsquamous non-small-cell lung cancer. NEJM 2015;373:1627-1639.
4. Larkin J, Chiarion-Sileni V, Gonzalez R, et al. Combined nivolumab and ipilimumab or monotherapy in untreated melanoma. NEJM 2015;373:23-34.

DRUG UPDATE

FDA WARNING: LOPERAMIDE & RARE CARDIAC ADVERSE EVENTS

The US Food and Drug Administration (FDA) has recently issued a warning that loperamide can cause rare serious cardiac events, particularly when taken in high doses for an extended period of time.[1] This prompted BCCA Provincial Drug Information to evaluate BCCA's loperamide dosing recommendations for the management of chemotherapy-induced diarrhea. Review of the FDA warning and the literature showed that most of the serious reported cases involved dosing that far exceeded the dosing recommended by the BCCA. Therefore, Provincial Drug Information concludes that it is safe to continue using loperamide at the current BCCA recommended doses.

BCCA Recommendations:
The Canadian loperamide product label recommends a standard maximum dose of 16 mg per day. However, the BCCA recommends a higher maximum daily dose of 24 mg for the acute treatment of chemotherapy-induced diarrhea which is necessary to prevent serious complications from chemotherapy-induced diarrhea (e.g. dehydration, electrolyte disturbances). [2]

FDA Warning and Literature Review:
Serious cardiac events that have been reported include QT prolongation resulting in Torsades de Pointes (TdP), cardiac arrest and death. However, the overall incidence of these events remains low, with only 48 cases reported to FDA over the past 39 years.[1] Serious cardiac events mainly occurred with loperamide misuse (e.g. to achieve opioid effects), high daily doses ranging from 64 mg to 1600mg (about 3 to 60 times the maximum BCCA recommended dose), and prolonged use over weeks to months. [1,3,4] These cases were generally associated with serum loperamide levels that were significantly higher (22-210 ng/mL) [5,6] than individuals who received single doses of 8 mg to 16 mg of loperamide (1.18-3.35 ng/mL).[7,8] It is anticipated that these levels would also be higher than what would be expected from someone using the BCCA's recommended maximum daily dose of 24mg.

Evidence indicates that serious cardiac events are extremely rare (11 cases) in individuals receiving therapeutic doses of loperamide. Four cases involved patients taking concomitant medications, which increased the serum loperamide level (e.g. CYP3A4, CYP2C8 or P-glycoprotein inhibitors), and 7 cases had limited details on specific risk factors.[1]

Overall, the risk of uncontrolled complications from chemotherapy-induced diarrhea is likely far greater than the rare cardiac risk that is generally associated with the chronic misuse of much higher doses of loperamide.

Submitted by: Jolene Guenter, BSc(Pharm)
BCCA Pharmacy Resident

References:
1. US Food and Drug Administration. FDA MedWatch - Loperamide (Imodium): Drug Safety Communication - Serious Heart Problems With High Doses From Abuse and Misuse. 2016. Accessed 01/24, 2017 http://www.fda.gov/Drugs/DrugSafety/ucm504617.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery
2. BCCA Guidelines for Management of Chemotherapy–induced Diarrhea. 2004; Available at http://www.bccancer.bc.ca/nursing-site/Documents/GuidelinesforManagementofCID.pdf. Accessed 02/16,2017
3. Spinner HL, Lonardo NW, Mulamalla R, Stehlik J. Ventricular tachycardia associated with high-dose chronic loperamide use. Pharmacotherapy 2015;35(2):234-238.
4. Mukarram O, Hindi Y, Catalasan G, Ward J. Loperamide induced Torsades de Pointes: a case report and review of the literature. Case Rep Med Epub 2016 Feb 18.
5. Eggleston W, Nacca N, Marraffa JM. Loperamide toxicokinetics: serum concentrations in the overdose setting. Clin Toxicol 2015;53(5):495-

496.
6. Marraffa JM, Holland MG, Sullivan RW, et al. Cardiac conduction disturbance after loperamide abuse. Clin Toxicol 2014;52(9):952-957.
7. Doser K, Meyer B, Nitsche V, BinkertGraber P. Bioequivalence evaluation of two different oral formulations of loperamide (Diarex Lactab vs Imodium capsules). Int J Clin Pharmacol Ther 1995;33(8):431-436.
8. Yu JH, Kim HJ, Lee S, Hwang S, et al. LC–MS determination and bioavailability study of loperamide hydrochloride after oral administration of loperamide capsule in human volunteers. J Pharm Biomed Anal 2004;36(2):421-427.

MEDICATION SAFETY CORNER

BCCA IMPLEMENTATION OF NEW CLOSED-SYSTEM DRUG TRANSFER DEVICE (ICU MEDICAL'S CHEMOLOCK™)

To further reduce occupational exposure of hazardous drugs and repetitive strain injuries experienced by healthcare staff, the BCCA is implementing a new Closed-System Drug Transfer Device (CSDTD) across all six regional cancer centres.

Studies have demonstrated that healthcare workers can develop negative health effects from the exposure to hazardous drugs despite complying with work practice guidelines and wearing personal protective equipment. The use of CSDTDs can prevent the escape of solutions, aerosols and vapours during the preparation, administration and disposal of hazardous drugs. The CSDTD facilitates the transfer of a drug from a vial to an infusion bag/syringe, and from an infusion bag/syringe into a patient, so that the transfer of drug is completely enclosed.

After careful consideration of several CSDTDs on the Canadian market, the BCCA has chosen to implement the ICU Medical's ChemoLock™ system. This decision aligns with those from the other BC health authorities. The ChemoLock™ CSDTD provides a leak-proof system for healthcare providers to prepare and administer hazardous drugs. Implementation of the ChemoLock™ system will occur sequentially across the six regional BC Cancer Agency centres over the next 4 months. The first implementation site will be Abbotsford Center on 27 Feb 2017. Implementation at the remaining sites will occur approximately every 2 to 3 weeks thereafter.

Submitted by: Sylvie Labelle-Stimac (BScPharm, MHSc, RPh)
Pharmacy Professional Practice Leader, BCCA – Abbotsford Centre

UPDATED BCCA HAZARDOUS DRUG LIST

Effective 1 March 2017, the BCCA Hazardous Drug List has been updated to reflect major changes in the 2016 edition of the *National Institute of Occupational Safety and Health (NIOSH) List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings*. Further review of the BCCA Hazardous Drug List is in progress.

Key updates to the BCCA Hazardous Drug List include (see table next page):

MEDICATION SAFETY CORNER

Updates	BCCA Benefit Drugs Affected		
Antineoplastic drugs added to the BCCA Hazardous Drug List (table 1)	Afatinib Axitinib Carfilzomib Dabrafenib	Enzalutamide Pertuzumab Pomalidomide Regorafenib	Trametinib Vismodegib
Drugs deleted from the BCCA Hazardous Drug List as they did not meet the hazardous drug criteria in the NIOSH 2016 Hazardous Drug list	Anagrelide Ibrutinib Ipilimumab	Nivolumab Obinutuzumab Ofatumumab	Pembrolizumab Tociluzumab

For further information about the revised hazardous drug list, please see the *BCCA Provincial Pharmacy Directive VI-80 – Hazardous Drug List* (internal document), and the *NIOSH List of Antineoplastic and Other Hazardous Drugs in Health Care Settings 2016*. To learn more about the BCCA Hazardous Drug List review process, please see the June 2011 issue of the Systemic Therapy Update.

COMMUNITIES ONCOLOGY NETWORK

REMINDER: OSCAR SUBMISSION DEADLINE – 5 APRIL 2017

The 2016-17 fiscal year will end on Friday, 31 March 2017. To meet the deadlines for external reporting to the Ministry of Health, all claims for drug reimbursement for the fiscal year must be invoiced by 11:59 pm on Wednesday, 5 April 2017 via OSCAR (Online System for Cancer drugs Adjudication and Reimbursement). Any claims invoiced after this date will not be eligible for reimbursement. For more information, please contact oscar@bccancer.bc.ca.

CANCER DRUG MANUAL

NEW MONOGRAPHS AND PATIENT HANDOUTS

The **Nivolumab Monograph** and **Patient Handout** have been developed with expert review provided by Dr. Kerry Savage (Medical Oncologist) and Robert Tillmanns (Pharmacist) from the BCCA Melanoma Tumour Group. Nivolumab is an IgG monoclonal antibody that inhibits PD-1 receptors from binding to ligands expressed on antigen-presenting or tumour cells. Nivolumab re-stimulates tumour-specific cytotoxic T lymphocytes and reactivates anti-tumour immunity. It is given as an intravenous infusion. Common side effects include pruritus, rash and diarrhea. Less common, but more severe, immune-related adverse reactions include pneumonitis, hepatitis, hypophysitis, colitis, nephritis and thyroiditis. These side effects can be severe and potentially fatal if not treated promptly. Should any of these side effects occur, nivolumab should be stopped and appropriate supportive care medications initiated as required. Patients must be strongly advised to report all toxicities and to not self-manage without medical advice. Guidelines for the management of immune-mediated adverse reactions can be found in the appendix of the associated BCCA Chemotherapy Protocols.

CANCER DRUG MANUAL

REVISED MONOGRAPHS AND PATIENT HANDOUTS

Highlights of key changes and/or updates to the Monographs and Patient Handouts are listed below:

Imatinib, Dasatinib and Nilotinib Monographs:

- Cautions on pregnancy, contraception and hepatitis B virus reactivation added

Capecitabine Monograph:

- *Supply and Storage* section – added instructions on preparation of oral solution for patients with difficulty swallowing

Etoposide Monograph:

- *Solution Preparation and Compatibility* section – moved instructions for the preparation of oral solution from *Dosage* section

Dexrazoxane Monograph and **Chemotherapy Preparation and Stability Chart:**

- *Parenteral Administration* table – updated route of administration as per new product information from manufacturer
- *Chemotherapy Preparation and Stability Chart* – revised vial stability as per new product information from manufacturer

Filgrastim Handout:

- Added GRASTOFIL® brand
- Updated storage temperature as per new product information from manufacturer (previously 24 hours, now 14 days)

BENEFIT DRUG LIST

NEW PROGRAMS

Effective 1 March 2017, the following BCCA treatment programs have been added to the BCCA Benefit Drug List:

Protocol Title	Protocol Code	Benefit Status
Treatment of Metastatic or Advanced Renal Cell Carcinoma Using Nivolumab	UGUAVNIV	Restricted
Treatment of Advanced Non-Small Cell Lung Cancer Using Nivolumab	ULUAVNIV	Restricted
Treatment of Unresectable or Metastatic Melanoma Using Nivolumab	USMAVNIV	Restricted

Benefit Drug List

Revised Programs

Effective 1 March 2017, the following BCCA treatment programs have been revised in the BCCA Benefit Drug List:

Protocol Title	Protocol Code	Benefit Status
Palliative Combination Chemotherapy for Advanced Pancreatic Adenocarcinoma Using Irinotecan, Oxaliplatin, Fluorouracil and Leucovorin	GIFIRINOX	Class I (Previously Restricted)
First Line Treatment of Locally Advanced and Metastatic Pancreatic Cancer with PACLitaxel-Nab (ABRAXANE®) and Gemcitabine	GIPGEMABR	Class I (Previously 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 treatment requiring BCCA Compassionate Access Program approval are prefixed with the letter "U".

New Protocols, PPPOs and Patient Handouts (Affected Documents are Checked)

CODE	Protocol	PPPO	Patient Handout	Protocol Title
UGUAVNIV	☑	☑	☑	Treatment of Metastatic or Advanced Renal Cell Carcinoma Using Nivolumab
ULUAVNIV	☑	☑	☑	Treatment of Advanced Non-Small Cell Lung Cancer Using Nivolumab
USMAVNIV	☑	☑	☑	Treatment of Unresectable or Metastatic Melanoma Using Nivolumab

Revised Protocols, PPPOs and Patient Handouts (Affected Documents are Checked)

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
BRAVGEMP	☑	☑	☐	Gemcitabine dosing clarified	Palliative Therapy for Metastatic Breast Cancer Using CISplatin and Gemcitabine
CNAJTZRT	☑	☐	☐	*Minor typo corrected*	Concomitant (Dual Modality) and Adjuvant Temozolomide for Newly Diagnosed Malignant Gliomas with Radiation

REVISED PROTOCOLS, PPPOS AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED)					
CODE	**Protocol**	**PPPO**	**Patient Handout**	**Changes**	**Protocol Title**
CNETO	☑	☑	☐	*Reformatted with various clarifications*	Palliative Treatment of Patients with Recurrent Malignant Gliomas and Ependymoma Using Low Dose Etoposide
GICIRB	☑	☐	☐	*Treatment duration updated*	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Irinotecan, Bevacizumab and Capecitabine
GICOXB	☑	☐	☐	*Treatment duration updated*	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Oxaliplatin, Bevacizumab and Capecitabine
GIFFIRB	☑	☐	☐	*Treatment duration updated*	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Irinotecan, Fluorouracil, Leucovorin and Bevacizumab
GIFFOXB	☑	☐	☐	*Treatment duration updated*	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Oxaliplatin, Fluorouracil, Leucovorin and Bevacizumab
GIFIRINOX	☑	☑	☑	*Eligibility, Exclusions, Dose Modifications, Precautions, drug intreactions updated*	Palliative Combination Chemotherapy for Advanced Pancreatic Adenocarcinoma Using Irinotecan, Oxaliplatin, Fluorouracil and Leucovorin
GIGAVCC	☑	☑	☑	*Eligibility, Tests, Premedications, Capecitabine Dose Calculation Table, Dose Modifications section, and Renal Dysfunction Table updated*	Palliative Therapy for Metastatic or Locally Advanced Gastric or Gastroesophageal Junction Adenocarcinoma Using CISplatin and Capecitabine
GIGAVCCT	☑	☑	☑	*Eligibility, Tests, Premedications, Capecitabine Dose Calculation Table, and Renal Dysfunction Table updated*	Palliative Treatment of Metastatic or Inoperable, Locally Advanced Gastric or Gastroesophageal Junction Adenocarcinoma using CISplatin, Capecitabine and Trastuzumab
UGIOCTLAR	☑	☐	☐	*Minor typo corrected*	Symptomatic Management of Functional Carcinoid and Neuroendocrine Tumors of the GI Tract Using Octreotide (SANDOSTATIN LAR®)
GIPGEMABR	☑	☑	☑	*CAP requirement deleted*	First-Line Treatment of Locally Advanced and Metastatic Pancreatic Cancer with PACLitaxel-Nab (ABRAXANE®) and Gemcitabine
GUEVER	☑	☐	☐	*Eligibility updated*	Therapy for Advanced Renal Cancer Using Everolimus
ULKCMLD	☑	☐	☐	*Tests, Supportive Medications and Precautions updated*	Treatment of Chronic Myeloid Leukemia and Ph+ Acute Lymphoblastic Leukemia Using daSATinib

REVISED PROTOCOLS, PPPOS AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED)					
CODE	**Protocol**	**PPPO**	**Patient Handout**	**Changes**	**Protocol Title**
LKCMLI	☑	☐	☐	*Exclusions, Tests, Supportive Medications and Precautions updated*	Treatment of Chronic Myeloid Leukemia and Ph+ Acute Lymphoblastic Leukemia Using iMAtinib
ULKCMLN	☑	☑	☐	*Tests, Supportive Medications and Precautions updated*	Treatment of Chronic Myeloid Leukemia Using niLOtinib
LULACATRT	☑	☑	☐	*Size of filter specified, return appointments clarified*	Treatment of Locally Advanced Non-Small Cell Lung Cancer Using CARBOplatin and PACLitaxel with Radiation Therapy
LYRITUX	☑	☐	☐	*Eligibility updated*	Treatment of Lymphoma with Single-Agent riTUXimab
ULYROMI	☑	☐	☐	*Minor typos corrected*	Treatment of Relapsed or Refractory Peripheral T-Cell Lymphoma (PTCL) with Romidepsin
SAAJGI	☑	☐	☐	*Contact physician, Exclusions, Tests, Supportive Medications and Precautions updated*	Adjuvant Treatment of C-Kit Positive High-Risk Gastrointestinal Stromal Cell Tumours Using iMAtinib
SAAVGI	☑	☐	☐	*Contact physician, Exclusions, Tests, Supportive Medications and Precautions updated*	Treatment of Advanced C-Kit Positive and C-Kit Negative Gastrointestinal Stromal Cell Tumours (GISTs) Using iMAtinib
SAAVGIDD	☑	☐	☐	*Contact physician, Exclusions, Tests, Supportive Medications and Precautions updated*	Treatment of Advanced c-kit positive Gastrointestinal Stromal Cell Tumours (GIST's) Using 800 mg Dosing of iMAtinib
USMAVFIPI	☑	☐	☐	*Eligibility and toxicities management updated*	First-Line Treatment of Unresectable or Metastatic Melanoma Using Ipilimumab
USMAVI	☑	☐	☐	*Exclusions, Tests, Supportive Medications and Precautions updated*	Treatment of Advanced C-Kit Positive Melanoma Using iMAtinib
USMAVIPI	☑	☐	☐	*Eligibility and toxicities management updated*	Treatment of Unresectable or Metastatic Melanoma Using Ipilimumab
USMAVPEM	☑	☐	☐	*Toxicities management updated*	Treatment of Unresectable or Metastatic Melanoma Using Pembrolizumab

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, 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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Compassionate Access Program (CAP)	604-877-6277	604-708-2026	cap_bcca@bccancer.bc.ca
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BCCA-Centre for the North	250-645-7300 Toll Free 888-775-7300		
BCCA-Fraser Valley Centre	604-930-2098 Toll Free 800-523-2885		
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