

Systemic Therapy Update

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For Health Professionals Who Care For Cancer Patients

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EDITOR'S CHOICE

NEW PROGRAMS

Effective 01 December 2018, the BC Cancer Provincial Systemic Therapy Program has approved the following treatment programs:

Head and Neck:

Vandetanib for Locally Advanced or Metastatic Medullary Thyroid Cancer (UHNOTVAN) — The BC Cancer Head and Neck Tumour Group has implemented a new treatment program for this uncommon cancer for which there was previously no standard of care. In a phase III randomized controlled trial (ZETA) that evaluated vandetanib against placebo, vandetanib demonstrated superior progression-free survival (median PFS not yet reached vs. 19.3 months, HR 0.46, 95% CI 0.31-0.69), but no difference in overall survival. Common or clinically significant toxicities included diarrhea (57%), hypertension (33%), and QT prolongation (16%), which were overall maneageable.

Due to reported cases of QT prolongation and Torsades de pointes, vandetanib is only available through the <u>Caprelsa Restricted Distribution Program</u>. Requirements under this program include:

- Prescribers must be certified by the program in order to prescribe vandetanib.
- Patients must be enrolled in the program by a certified physician.
- Pharmacists do not require certification, but may access online training.

EDITOR'S CHOICE

Leukemia:

Therapy of FLT3+ Acute Myeloid Leukemia using Midostaurin in Combination with Induction and Consolidation Chemotherapy (ULKAMLMIDO) – The BC Cancer Leukemia and Bone Marrow Transplant Tumour Group has introduced this new regimen for patients with newly diagnosed acute myeloid leukemia with FMS-like tyrosine kinase 3 (FLT3) mutation. Disease harbouring the FLT3 gene mutation is associated with higher relapse rates and poor overall survival. ² In this treatment regimen, midostaurin (a FLT3 inhibitor) is used in combination with standard cytarabine and daunorubicin induction chemotherapy, and with standard high- or intermediate-dose cytarabine consolidation chemotherapy. In a randomized, double-blind, placebo-controlled trial, the addition of midostaurin to standard therapy significantly improved overall survival from 25.6 to 74.7 months (HR 0.78, p<0.009) and event-free survival from 3.0 to 8.2 months (HR 0.78, p<0.002).³

Commonly reported adverse effects included pancytopenia, diarrhea, exfoliative dermatitis hyperglycemia and infection. Most of these occurred at similar rates when standard chemotherapy was given with or without midostaurin. Only grade 3 and higher anemia (92.7% vs 87.8%) and rash/desquamation (14.1% vs 7.6%) occurred more frequently in the midostaurin group. In addition, rare, but serious, adverse effects included cardiac failure, interstitial lung disease/pneumonitis, and hypersensitivity reactions. QT prolongation has also been reported.

For more information about the pharmacology of midostaurin, please see the *Cancer Drug Manual* section below.

References:

- 1. Wells SA, Robinson BG, Gagel RF, et al. Vandetanib in patients with locally advanced or metastatic medullary thyroid cancer: a randomized, double-blind phase III trial. J Clin Oncol 2012;30:134-141.
- Pan-Canadian Oncology Drug Review. Final recommendation for midostaurin (Rydapt) for acute myeloid leukemia (AML). December 19, 2017.
- 3. Stone RM, Mandrekar SJ, Sanford BL, et al. Midostaurin plus chemotherapy for acute myeloid leukemia with a FLT3 mutation. N Engl J Med 2017;377:454-464.

REVISED PROGRAMS

Effective 01 December 2018, the BC Cancer Provincial Systemic Therapy Program has revised the following treatment program:

Supportive Care:

Updated BC Cancer Guidelines for Prevention and Treatment of Chemotherapy-Induced Nausea and Vomiting in Adults (SCNAUSEA) – SCNAUSEA has undergone significant revisions to reflect new treatment options available in current practice. These options include:

- Olanzapine as an additional agent for highly or moderately emetogenic chemotherapy (HEC or MEC), particularly if delayed nausea is a concern¹⁻³
- Netupitant/palonosetron*, an NK-1 antagonist/5-HT3 antagonist fixed-dose combination option for HEC, administered on day 1 only³
- Palonosetron as an alternate 5-HT3 antagonist option for HEC or MEC^{4,5}
- Prophylactic antiemetic regimens for oral chemotherapy³
- *BC PharmaCare is currently reviewing netupitant/palonosetron for benefit status; palonosetron and olanzapine (for antiemetic use) have non-benefit status.

EDITOR'S CHOICE

Additional updates include the revision of dexamethasone, prochlorperazine, and metoclopramide dosing^{3,5,6}, updated emetogenicity nomenclature³, and deletion of dolasetron (removed from Canadian market).

References:

- 1. Navari RM, Qin R, Ruddy KJ, et al. Olanzapine for the prevention of chemotherapy-induced nausea and vomiting. N Engl J Med 2016:375:134-42
- 2. Chiu L, Chow R, Popovic M, et al: Efficacy of olanzapine for the prophylaxis and rescue of chemotherapy-induced nausea and vomiting (CINV): A systematic review and meta-analysis. Support Care Cancer 24:2381-2392, 2016.
- 3. Ettinger D, Berger M, Aston J et al. NCCN Clinical Practice Guidelines in Oncology Antiemesis v.2.2018: National Comprehensive Cancer Network; Apr 30 2018.
- 4. Hesketh P, Kris M, Basch E et al. Antiemetics: American Society of Clinical Oncology (ASCO) Clinical Practice Guideline Update. J Clin Oncol Jul 31 2017; 35: 1-24.
- 5. Roila F, Molassiotis A, et al. 2016 MASCC and ESMO guideline update for the prevention of chemotherapy- and radiotherapy-induced nausea and vomiting and of nausea and vomiting in advanced cancer patients. Annals of Oncology 27 (Supplement 5): v119-v133; 2016.
- 6. Hoskins P. Antiemetic Guidelines. December 2017.

PROVINCIAL SYSTEMIC THERAPY PROGRAM POLICIES

New Patient Medication Handout Selection Policy

The Provincial Systemic Therapy Program Policy III-160 – Selecting Patient Medication Handouts has been created and can be found on the BC Cancer Systemic Therapy website. The policy replaces Provincial Pharmacy Directive III-30-11 – Stepwise Approach To Selecting Patient Medication Handouts. Patient medication information handouts are available for most systemic therapy drugs via the Cancer Drug Manual on the BC Cancer website. Where they do not exist, this policy has been created to guide healthcare professionals on the selection of patient handouts from alternative drug databases.

BENEFIT DRUG LIST

New Programs

Effective 01 December 2018, the following treatment programs have been added to the BC Cancer Benefit Drug List:

Protocol Title	Protocol Code	Benefit Status
Treatment for Locally Advanced or Metastatic Medullary Thyroid Cancer using Vandetanib	UHNOTVAN	Restricted
Therapy of FLT3+ Acute Myeloid Leukemia using Midostaurin in Combination with Induction and Consolidation Chemotherapy	ULKAMLMIDO	Restricted

BENEFIT DRUG LIST

REVISED PROGRAMS

Effective 01 December 2018, the following treatment programs have been revised in the BC Cancer Benefit Drug List:

Protocol Title	Protocol Code	Benefit Status
Second-Line Therapy for Metastatic or Locally Advanced Gastric or Gastroesophageal Junction Cancer using Weekly Paclitaxel and Ramucirumab	GIGAVRAMT	Class I (previously restricted)
Perioperative Treatment of Resectable Adenocarcinoma of the Stomach, Gastroesophageal Junction or Lower 1/3 Esophagus using Docetaxel, Oxaliplatin, Infusional Fluorouracil, and Leucovorin	GIGFLODOC	Class I (previously restricted)

CANCER DRUG MANUAL

New Monographs and Patient Handouts

All BC Cancer Drug Manual Monographs and Patient Handouts can be accessed <u>online</u> in the BC Cancer Drug Index.

The **Midostaurin Monograph** and **Patient Handout** have been developed with expert review provided by Dr. David Sanford (hematologist) and Judith Nyrose (pharmacist) of the BC Cancer Leukemia and Bone Marrow Transplant Tumour Group. Midostaurin is a multi-targeted oral tyrosine kinase inhibitor which inhibits FMS-like tyrosine kinase 3 (FLT3) receptor signalling. Midostaurin is used in combination with standard induction and consolidation chemotherapy for the treatment of FLT3-mutated acute myeloid leukemia. Administration with food is recommended to decrease the risk of nausea and vomiting. As numerous CYP P450 interactions are possible, it is advised to review concurrent therapy for drug-drug interactions. For information about the toxicity profile of midostaurin, please see the *Editor's Choice* section above.

The **Ribociclib Monograph and Patient Handout** have been developed with expert review provided by Khushminder Rai (pharmacist) of the BC Cancer Breast Tumour Group. Ribociclib is an orally administered, selective, reversible small molecule inhibitor of cyclin-dependent kinases (CDK) 4 and 6. Ribociclib is used in combination with letrozole as initial endocrine-based therapy for hormone receptorpositive, HER2-negative metastatic breast cancer in postmenopausal women. The usual dose is 600 mg orally once daily for 21 days of a 28-day cycle (letrozole is dosed continuously). Administration in the morning is recommended as QT-prolongation risk may be increased when ribociclib is taken in the evening due to bradycardia, which naturally occurs during sleep.

Highlights of these documents include:

- QT prolongation has been reported; correct electrolytes and monitor ECG in patients with risk factors for QT prolongation or Torsades de pointes, including those taking other QT-prolonging drugs
- Myelosuppression (including anemia, neutropenia, thrombocytopenia) has been frequently reported

CANCER DRUG MANUAL

Rare, but serious, side effects include hepatotoxicity and pulmonary embolism

Ribociclib is <u>NOT</u> a BC Cancer Benefit Drug, and requires application to the BC Cancer Compassionate Access Program. Its Interim Monograph and Patient Handout are made available for reference only.

REVISED MONOGRAPHS AND PATIENT HANDOUTS

Highlights of key changes and/or updates to the Monographs, Patient Handouts and Chemotherapy Preparation and Stability Chart (CPSC) are listed below:

Idelalisib Monograph and Patient Handout:

- Cautions: added animal data from carcinogenicity studies
- Side Effects: added progressive multifocal leukoencephalopathy (PML)
- Handout: added symptoms of PML to bulleted sections

Methotrexate CPSC:

Updated Hospira brand to reflect merger with Pfizer

Nivolumab Monograph and CPSC:

- Solution Preparation and Compatibility: added information related to compendial endotoxin limits and compounded bag sizes
- Chemotherapy Preparation and Stability Chart: added suggested bag volumes and recommendation to protect compounded product from light during storage periods

Ruxolitinib Monograph:

- Interactions: updated table to include more details regarding interaction management, including suggested dose reductions
- Supply and Storage: added new tablet strength
- Dosing: added dosing for polycythemia vera; updated dosing for myelosuppression, renal and hepatic failure, and dialysis

Vandetanib Monograph:

Dosing: updated to include new BC Cancer protocol and standard dosing

LIST OF REVISED PROTOCOLS, PRE-PRINTED ORDERS AND PATIENT HANDOUTS

BC Cancer 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 BC Cancer 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		
UHNOTVAN	$\overline{\checkmark}$	$\overline{\checkmark}$	V	Treatment for Locally Advanced or Metastatic Medullary Thyroid Cancer using Vandetanib		
ULKAMLMIDO	$\overline{\checkmark}$	$\overline{\checkmark}$		Therapy of FLT3+ Acute Myeloid Leukemia using Midostaurin in Combination with Induction and Consolidation Chemotherapy		

REVISED PROTOCOLS, PPPOS AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED)						
CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title	
UBRAJTTW	\square	$\overline{\checkmark}$		Premedications clarified	Adjuvant Therapy for Breast Cancer using Weekly Paclitaxel and Trastuzumab (HERCEPTIN™)	
GIEFUPRT				Return Appointment Orders section revised	Combined Modality Therapy for Locally Advanced Esophageal Cancer using Cisplatin, Infusional Fluorouracil and Radiation Therapy	
GIFUART	\square		V	Various updates	Curative Combined Modality Therapy for Carcinoma of the Anal Canal using Mitomycin, Infusional Fluorouracil and Radiation Therapy	
GIFUPART				Tests updated	Curative Combined Modality Therapy for Carcinoma of the Anal Canal using Cisplatin, Infusional Fluorouracil and Radiation Therapy	
GIGAVRAMT			\square	CAP requirement deleted	Second-Line Therapy for Metastatic or Locally Advanced Gastric or Gastroesophageal Junction Cancer using Weekly Paclitaxel and Ramucirumab	
GIGFLODOC	V	V	V	CAP requirement deleted	Perioperative Treatment of Resectable Adenocarcinoma of the Stomach, Gastroesophageal Junction or Lower 1/3 Esophagus using Docetaxel, Oxaliplatin, Infusional Fluorouracil, and Leucovorin	
UGIYTT	$\overline{\checkmark}$			Invoicing information deleted	Yttrium-90 for Transarterial Radioembolisation (TARE)	
GOCXAJCAT		Ø		Formatting updated	Primary Adjuvant Treatment of Adenocarcinoma/ Adenosquamous Cancer of the Cervix with Carboplatin and Paclitaxel Preceding or Following Irradiation with or without Cisplatin	

REVISED PROTOC	ols , PPPO s	AND PATIEN	T HANDOUT	UTS (AFFECTED DOCUMENTS ARE CHECKED)		
CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title	
UGOOVBEVLD				Line priming clarified	Treatment of Platinum Resistant Epithelial Ovarian Cancer with Bevacizumab and Doxorubicin Pegylated Liposomal (CAELYX™)	
GOOVCAD		Ø		Return Appointment Orders section revised	Primary Treatment with Visible or No Visible Residual Tumour (Moderate, High, or Extreme Risk) or Treatment at Relapse of Invasive Epithelial Ovarian, Fallopian Tube, and Primary Peritoneal Cancer, using Carboplatin and Docetaxel	
GOOVCAG				Number of treatment cycles and Protocol Title revised	Carboplatin and Gemcitabine for the Treatment of Recurrent Platinum-Sensitive Ovarian Cancer	
GOOVCARB				Return Appointment Orders section revised	First- or Second-Line Therapy for Invasive Epithelial Ovarian Cancer using Single-Agent Carboplatin	
GOOVCATM		Ø		Return Appointment Orders section revised	Primary Treatment of Invasive Epithelial Ovarian, Fallopian Tube and Primary Peritoneal Cancer, with No Visible Residual Tumour (Moderate-High Risk) using Carboplatin and Paclitaxel	
GOOVCATX		Ø		Return Appointment Orders section revised	Primary Treatment of Visible Residual (Extreme Risk) Invasive Epithelial Ovarian, Fallopian Tube or Peritoneal Cancer using Carboplatin and Paclitaxel	
GOOVCIS	$\overline{\checkmark}$			Number of treatment cycles revised	Therapy for Invasive Epithelial Ovarian Cancer using Cisplatin	
GOOVCYCPO	Ø			Number of treatment cycles revised	Palliative Therapy for Relapsed/Progressing Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Carcinoma using Metronomic Low-Dose Oral Cyclophosphamide	
GOOVDDCAT				Return Appointment Orders section revised	Treatment Of Advanced Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Carcinoma using Carboplatin and Weekly Paclitaxel	
GOOVDOC				Number of treatment cycles revised	Treatment of Relapsed/Progressing Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Carcinoma using Docetaxel	
GOOVETO				Number of treatment cycles revised	Treatment of Relapsed/Progressing Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Carcinoma using Etoposide	
GOOVFPLDC				Return Appointment Orders section revised	First-Line Treatment of Epithelial Ovarian Cancer using Doxorubicin Pegylated Liposomal (CAELYX™) and Carboplatin	
GOOVGEM				Number of treatment cycles revised	Treatment of Relapsed/Progressing Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Carcinoma using Gemcitabine	

REVISED PROTOCOLS, PPPOS AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED)						
CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title	
GOOVLDOX				Number of treatment cycles revised	Treatment of Epithelial Ovarian Cancer Relapsing after Primary Treatment using Doxorubicin Pegylated Liposomal (CAELYX™)	
GOOVTAX3				Number of treatment cycles revised	Treatment of Relapsed/Progressing Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Carcinoma using Paclitaxel	
GOOVTOP	\square			Number of treatment cycles revised	Treatment of Relapsed/Progressing Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Carcinoma using Topotecan	
GOOVVIN				Number of treatment cycles revised	Treatment of Relapsed/Progressing Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Carcinoma using Vinorelbine	
GUFUPRT	V	V	V	Institution name, Tests, Treatment, and Contact Physician revised; TALLman lettering updated	Combined Modality Therapy for Squamous Cell Cancer of the Genitourinary System using Fluorouracil and Cisplatin with Radiation	
HNAVPC	Ø	Ø		Tests and cisplatin preparation revised	Treatment for Unresectable, Locoregionally Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck using Paclitaxel and Cisplatin or Carboplatin	
HNLAALTPRT				Institution name, Tests and cisplatin preparation revised	Locally Advanced (Alternate) Head and Neck Cancer using Cisplatin During Radiation Therapy	
HNNAVPG				Institution name, Tests and cisplatin preparation revised	Treatment of Locoregionally Recurrent and/or Metastatic Nasopharyngeal Cancer with Platinum and Gemcitabine	
HNSAVNP	Ø	Ø		Institution name revised; cisplatin preparation and infusion time clarified	Palliative Treatment of Advanced Salivary Gland Cancers with Cisplatin and Vinorelbine	
ULUAVNIV	V			Eligibility clarified	Treatment of Advanced Non-Small Cell Lung Cancer using Nivolumab	
ULUAVNIV4				Eligibility clarified	Treatment of Advanced Non-Small Cell Lung Cancer using 4-Weekly Nivolumab	
ULUAVOSI	Ø			Tests revised	Treatment of EGFR T790M Mutation-Positive Advanced Non-Small Cell Lung Cancer (NSCLC) with Osimertinib	
LUSCCAV	V	Ø		Tests, Institution name/logo, Contact Physician updated	Treatment of Extensive Small Cell Lung Cancer (SCLC) with Cyclophosphamide, Doxorubicin and Vincristine (CAV)	

REVISED PROTOCOLS, PPPOS AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED)						
CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title	
LUSCPE			\square	Tests, Institution name/logo, Contact Physician updated	Treatment of Extensive Stage Small Cell Lung Cancer (SCLC) with Cisplatin and Etoposide	
LUSCPI			V	Tests, Institution name/logo, Contact Physician updated	Second-Line Treatment of Extensive Stage Small Cell Lung Cancer (SCLC) with Irinotecan with or without Platinum	
LUSCPOE				Tests, Institution name/logo, Contact Physician updated	Palliative Therapy of Extensive Stage Small Cell Lung Cancer (SCLC) with Oral Etoposide	
LUSCTOP			$\overline{\mathbf{A}}$	Tests, Institution name/logo, Contact Physician updated	Second-line Treatment of Recurrent Small Cell Lung Cancer (SCLC) with Topotecan	
LYCHOPR				Eligibility clarified	Treatment of Lymphoma with Doxorubicin, Cyclophosphamide, Vincristine, Prednisone and Rituximab (CHOP-R)	
LYCVPPABO	$\overline{\checkmark}$			Treatment and Institution name revised	Treatment of Hodgkin Lymphoma with Cyclophosphamide, Vinblastine, Procarbazine and Prednisone	
ULYRITZ				Drug availability updated	Palliative Therapy for Lymphoma using Radioimmunotherapy: Rituximab-Priming for Ibritumomab ⁹⁰ Y (ZEVALIN™)	
UMYLDF	Ø			Tests and Institution name revised	Treatment of Previously Untreated Multiple Myeloma and Not Eligible for Stem Cell Transplant using Lenalidomide with Low-Dose Dexamethasone	
UMYLDREL				Treatment, Tests and Institution name revised	Therapy of Relapsed Multiple Myeloma using Lenalidomide with Dexamethasone	
UMYPOMDEX	\square	$\overline{\checkmark}$		Tests and Institution name revised	Therapy of Multiple Myeloma using Pomalidomide with Dexamethasone	
SAAVGI	$\overline{\checkmark}$			Typo corrected in Dose Modifications	Treatment of Advanced C-Kit Positive and C-Kit Negative Gastrointestinal Stromal Cell Tumours (GISTs) using Imatinib	
SAVAC		Ø		Return Appointment Orders section and Institution logo revised	Treatment of Sarcomas with Vincristine, Doxorubicin and Cyclophosphamide (SAVAC)	
SCNAUSEA	Ø			New treatment options added; multiple other revisions	Prevention and Treatment of Chemotherapy- Induced Nausea and Vomiting in Adults	

Website Resources and Contact Information

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BC Cancer-Kelowna	250-712-3900 Toll Free 888-563-7773		
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