Systemic Therapy Update



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For Health Professionals Who Care For Cancer Patients

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- UMYLENMTN, USMAVFIPI, USMAVIPI; <u>List of revised</u> GI protocols with updated information on capecitabine and fluorouracil associated diarrhea: GIAJCAP, GIAJCAPOX, GIAJFFOX, GIAJFL, GIAVCAP, GIAVFL, GIAVTZCAP, GICAPOX, GICART, UGICOXB, GICPART, GIEFUPRT, UGIFFOXB, GIFOLFOX, GIFUART, GIFUC, GIFUFA, GIFUIP, GIFUPART, GIGAIRT, GIGAJCC, GIGAJCPRT, GIGAVCC, GIGAVCCT, GIGAVCFT, GIGAVCCC, GIGAVECF, GIGECC, GIGECF, GIHIPEC, GIRAJCOX, GIRAJFFOX, GIRCAP, GIRCRT, GIRINFRT
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EDITOR'S CHOICE

New Programs

The Provincial Systemic Therapy Program has approved the following program effective 1 November 2015:

Lymphoma/Multiple Myeloma:

Bortezomib Maintenance for Multiple Myeloma (UMYBORMTN) – Bortezomib offers an alternative to the currently funded lenalidomide maintenance therapy (UMYLENMTN) for high-risk multiple myeloma after stem cell transplant. Patients must have confirmed chromosomal abnormalities of del (17p) or t(4;14). In a subset analysis of a phase III trial, maintenance bortezomib post-transplant was associated with increased progression free survival (26.2 vs. 12.0 months). At the BC Cancer Agency, bortezomib is the preferred agent for patients with these high-risk chromosomal abnormalities, but lenalidomide remains an option recognizing the convenience of oral therapies.

Reference:

K Neben, HM Lokhorst, A Jauch, et al. Administration of bortezomib before and after autologous stem cell transplantation improves outcome in multiple myeloma patients with deletion 17p. Blood 2012;119(4):940-948.

DRUG UPDATE

LETTER TO PHYSICIANS: WARFARIN MONITORING IN PATIENTS ON GI CAPECITABINE PROTOCOLS

A "Warfarin Monitoring Letter" to physicians will be available on the BCCA website with all the Gastrointestinal Protocols containing capecitabine. Capecitabine can reduce the metabolism of warfarin through inhibition of the cytochrome P450 2C9 enzyme. Increased INR monitoring may be required in patients treated with concurrent capecitabine and warfarin therapies.

Large INR changes and severe bleeding have been reported. These effects have been seen days to months after initiating capecitabine as well as within 1 month of stopping capecitabine. Therefore, it is important that non-BCCA physicians who prescribe warfarin are aware of the increased risk and monitoring required for patients treated concurrently with capecitabine. The letter shall be given to patients receiving a GI capecitabine regimen to bring to their family physician.

CANCER DRUG MANUAL

REVISED MONOGRAPHS AND PATIENT HANDOUTS

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

Anagrelide Monograph and Patient Handout

- Monograph addition of Side Effects paragraphs for cardiovascular effects, hepatic metabolism, interstitial lung diseases, platelet counts, and renal abnormalities
- Patient Handout added information on QT-prolongation

Gefitinib Patient Handout

Administration instructions have been updated to delete the requirement for morning administration as per current product information. Patients are now instructed that gefitinib can be taken with food or on an empty stomach, and should be taken about the same time each day.

Ipilimumab Monograph and Patient Handout

- Monograph Thirty minute infusions: new paragraph added to Side Effects section and Parenteral Administration table updated. The frequency of reported infusion reactions may be slightly increased when ipilimumab is infused over 30 minutes (instead of the standard 90 minutes). As infusion reactions are reported with the second dose of ipilimumab, the infusion time should be reduced only if the patient has no reaction with cycle 2. Please refer to protocol for more details.
- Handout In the Management section for skin rashes, the patient is now directed to follow standard guidelines regarding sunscreen use and sun protection as per <u>recommendations</u> from the American Society of Clinical Oncology (ASCO).

Nivolumab Interim Monograph and CPSC

Updated information on the Canadian supplier, and that a Notice of Compliance has been granted

BENEFIT DRUG LIST					
New Programs					
The following program has been added to the Benefit Drug List effective 1 November 2015:					
Protocol Title	Protocol Code	Benefit Status			
Maintenance Therapy for Multiple Myeloma using Bortezomib for	LINAVDODNATNI	Do atriata d			

UMYBORMTN

Restricted

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

Patients with the High-Risk Chromosome Abnormality

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	PPPO	Patient Handout	Protocol Title	
UMYBORMTN	V	V		Maintenance Therapy for Multiple Myeloma using Bortezomib for Patients with the High-Risk Chromosome Abnormality	
USMAVFIPI				First-Line Treatment of Unresectable or Metastatic Melanoma Using Ipilimumab	

REVISED PROTOCOLS, PPPOS AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED):						
CODE	Protocol	PPPO	Patient Handout	Changes Protocol Title		
BRLATWAC		Ø		Cycle-specific information added	NEOAdjuvant Therapy for Locally Advanced Breast Cancer Using Weekly PACLitaxel Followed by DOXOrubicin and Cyclophosphamide	
GOOVAI	$\overline{\checkmark}$			Eligibility clarified	Therapy for Advanced Ovarian Cancer Using an Aromatase Inhibitor	
GOOVCADR	Ø			Eligibility clarified	Second Line Treatment Using DOCEtaxel and CARBOplatin for Epithelial Ovarian Cancer Relapsing after Primary Treatment	

REVISED PROTOCOLS, PPPOS AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED):						
CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title	
GOOVIPPC	V			Eligibility clarified	Primary Treatment of Stage III less than or equal to 1 cm Visible Residual Invasive Epithelial Ovarian Cancer or Stage 1 Grade 3 or Stage II Grade 3 Papillary Serous Ovarian Cancer Using Intravenous and Intraperitoneal PACLitaxel and Intraperitoneal CARBOplatin	
GOOVPLDC	Ø			Eligibility clarified	Second Line Treatment for Epithelial Ovarian Cancer Relapsing After Primary Treatment Using Pegylated Liposomal DOXOrubicin (PLD) and CARBOplatin	
GOOVTAM	\square			Eligibility clarified	Therapy for Advanced Ovarian Cancer Using Tamoxifen	
UMYLENDEX	\square			Minor misspelling corrected under Tests	Therapy of Multiple Myeloma Using Lenalidomide with Dexamethasone	
UMYLENMTN	Ø			Dose modification in renal dysfunction clarified, minor misspelling corrected under Tests	Maintenance Therapy of Multiple Myeloma Using Lenalidomide	
USMAVFIPI	$\overline{\checkmark}$			Infusion time and toxicities management updated	First-Line Treatment of Unresectable or Metastatic Melanoma Using Ipilimumab	
USMAVIPI	V	$ \overline{\checkmark} $	V	Infusion time and toxicities management updated	Treatment of Unresectable or Metastatic Melanoma Using Ipilimumab	

The following gastrointestinal protocols containing fluorouracil and capecitabine have been updated to include more information on the monitoring and management of drug-associated diarrhea, as well as the potential increased risk in patients with DPD deficiency.

CODE	Protocol Title
GIAJCAP	Adjuvant Therapy of Colon Cancer Using Capecitabine
GIAJCAPOX	Adjuvant Combination Chemotherapy for Stage III and Stage IIB Colon Cancer Using Oxaliplatin and Capecitabine
GIAJFFOX	Adjuvant Combination Chemotherapy for Stage III and Stage IIB Colon Cancer Using Oxaliplatin, Fluorouracil and Leucovorin
GIAJFL	Adjuvant Therapy of Colon Cancer Using Fluorouracil Injection and Infusion and Leucovorin Infusion
GIAVCAP	Palliative Therapy of Advanced Colorectal Cancer using Capecitabine
GIAVFL	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Fluorouracil Injection and Infusion and Leucovorin Infusion
GIAVTZCAP	Palliative Therapy of Metastatic Neuroendocrine Cancer Using Temozolomide and Capecitabine
GICAPOX	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Oxaliplatin and Capecitabine
GICART	Combined Modality Therapy for Carcinoma of the Anal Canal Using Mitomycin, Capecitabine and Radiation Therapy

CODE	Protocol Title
UGICOXB	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Oxaliplatin, Bevacizumab and Capecitabine
GICPART	Combined Modality Therapy for Carcinoma of the Anal Canal Using CISplatin, Capecitabine and Radiation Therapy
GIEFUPRT	Combined Modality Therapy for Locally Advanced esophageal Cancer Using Fluorouracil and CISplatin
UGIFFOXB	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Oxaliplatin, Fluorouracil, Leucovorin and Bevacizumab
GIFOLFOX	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Oxaliplatin, Fluorouracil and Leucovorin
GIFUART	Combined Modality Curative Therapy for Carcinoma of the Anal Canal Using Mitomycin, Fluorouracil and Radiation Therapy
GIFUC	Palliative Chemotherapy for Upper Gastrointestinal Tract Cancer (Gastric, Esophageal, Gall Bladder Carcinoma and Cholangiocarcinoma) and Metastatic Anal Cancer Using Infusional Fluorouracil and CISplatin
GIFUFA	Palliative Therapy for Advanced Colorectal Cancer Using Leucovorin and Fluorouracil
GIFUIP	Chemotherapy of Pseudomyxoma Peritonei Using Intraperitoneal Mitomycin and Fluorouracil
GIFUPART	Combined Modality Curative Therapy for Carcinoma of the Anal Canal Using CISplatin, Infusional Fluorouracil and Radiation Therapy
GIGAIRT	Combined Modality Adjuvant Therapy for Completely Resected Gastric Adenocarcinoma Using Fluorouracil and Folinic Acid (Leucovorin) and Radiation Therapy
GIGAJCC	Adjuvant Chemotherapy of Gastric Cancer Patients with D2 Resection (Node Negative) or Ineligible for Adjuvant Chemoradiation, Using CISplatin and Capecitabine
GIGAJCPRT	Adjuvant Chemotherapy of Gastric Cancer Patients with Completely Resected Gastric Cancer Using CISplatin and Capecitabine and Radiation Therapy
GIGAVCC	Palliative Therapy for Metastatic or Locally Advanced Gastric Cancer Using CISplatin and Capecitabine
GIGAVCCT	Palliative Treatment of Metastatic or Inoperable, Locally Advanced Gastric or Gastroesophageal Junction Adenocarcinoma using CISplatin, Capecitabine and Trastuzumab
GIGAVCFT	Palliative Treatment of Metastatic or Inoperable, Locally Advanced Gastric or Gastroesophageal Junction Adenocarcinoma using CISplatin, Infusional Fluorouracil and Trastuzumab
GIGAVECC	Palliative Therapy for Metastatic or Locally Advanced Gastric or Esophagogastric Cancer Using Epirubicin, CISplatin and Capecitabine
GIGAVECF	Palliative Therapy for Metastatic or Locally Advanced Gastric, Esophagogastric Cancer Using Epirubicin, CISplatin and Infusional Fluorouracil
GIGECC	Perioperative Treatment of Resectable Adenocarcinoma of the Stomach, Gastroesophageal Junction or Lower 1/3 Esophagus Using Epirubicin, CISplatin and Capecitabine
GIGECF	Perioperative Treatment of Resectable Adenocarcinoma of the Stomach, Gastroesophageal Junction or Lower 1/3 Esophagus Using Epirubicin, CISplatin and Infusional Fluorouracil
GIHIPEC	Hyperthermic Intraperitoneal Chemotherapy (HIPEC) for Patients with Peritoneal Carcinomatosis from Limited Advanced Colorectal and Appendiceal Carcinomas Using Oxaliplatin and Fluorouracil (5-FU)
GIRAJCOX	Adjuvant Combination Chemotherapy for Stage III Rectal Cancer Using Oxaliplatin and Capecitabine
GIRAJFFOX	Adjuvant Combination Chemotherapy for Stage III Rectal Cancer Using Oxaliplatin, Fluorouracil and Leucovorin
GIRCAP	Adjuvant Therapy for Stage II and III Rectal Cancer Previously Treated with Preoperative Radiation Therapy using Capecitabine
GIRCRT	Combined Modality Adjuvant Therapy for High Risk Rectal Carcinoma Using Capecitabine and Radiation Therapy
GIRINFRT	Combined Modality Adjuvant Therapy for High Risk Rectal Carcinoma Using Capecitabine, Infusional Fluorouracil and Radiation Therapy
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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			
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