

Systemic Therapy Update

Volume 23 Issue 10 October 2020

For Health Professionals Who Care for Cancer Patients

Inside This Issue:

Editor's Choice

New Programs: Enzalutamide for Non-Metastatic Castration-Resistant Prostate Cancer (UGUNMPENZ) | Capecitabine for Recurrent or Metastatic Squamous Cell Cancer of the Head and Neck (HNAVCAP)

Update: Influenza Vaccine Recommendations

Cancer Drug Manual[©]

Revised: Doxorubicin Pegylated Liposomal, Palbociclib,

Ribociclib

Benefit Drug List

New: GU: UGUNMPENZ | HN: HNAVCAP

Revised: LY: LYPEM, LYPEM6

NEW Protocols, PPPOs and Patient Handouts

GU: UGUNMPENZ | HN: HNAVCAP

REVISED Protocols, PPPOs and Patient Handouts

BR: BRAVABR, BRAVPTRAD | GI: GIAJCAPOX, GIAJFFOX, GICAPOX, GICOXB, GIEFFOXRT, UGIFFIRPAN, GIGAJCOX, GIGAVCOX, GIGAVCOXT, UGILEN, GIPGEMABR, GIRAJCOX | GO: GOOVBEVG, GOOVBEVLD | GU: UGUAVPEM, UGUAVPEM6, GUNAJPG, UGUPABI, UGUPAPA, GUPCABA, UGUPENZ | HN: UHNAVNIV, UHNAVNIV4, HNNAVPG | LY: LYCODOXMR, LYPEM, LYPEM6 | SM: USMAVFIPI, SMAVIPI, SMAVPEM, SMAVPEM6, SMMCCPE

Resources and Contact Information

Editor's Choice

New Programs

Effective 01 October 2020, the BC Cancer Provincial Systemic Therapy Program has approved the following new treatment programs. The full details of these programs can be found on the BC Cancer website in the Chemotherapy Protocols section.

Genitourinary

Enzalutamide for Non-Metastatic Castration-Resistant Prostate Cancer (UGUNMPENZ) — The BC Cancer Genitourinary Tumour Group is expanding the use of enzalutamide as a treatment option in patients with non-metastatic castration-resistant prostate cancer (nmCRPC). Previously, enzalutamide was approved only in the metastatic castration-resistant setting. Going forward, patients with nmCRPC may receive enzalutamide or apalutamide (UGUPAPA), but not their sequential use; androgen ablative therapy should be maintained with either treatment option (i.e., maintain LHRH agonist or LHRH antagonist). A BC Cancer Compassionate Access Program (CAP) approval is required. Note that patients who have progressed on enzalutamide in the non-metastatic setting are not eligible to receive enzalutamide (UGUPENZ) or abiraterone (UGUPABI) in the metastatic setting.

Approval of this new treatment program is based on the phase III PROSPER trial which compared enzalutamide to placebo in patients with nmCRPC.^{1,2,3} All patients without orchiectomy were maintained on androgen ablative therapy. The trial demonstrated significant improvement in the primary end point of median metastasis-free survival (mMFS) and in the final analysis of median overall survival (mOS) in the enzalutamide arm (mMFS: 36.6 months vs. 14.7 months, HR 0.29, 95% CI 0.24-0.35; mOS: 67 months vs 56.3 months, HR 0.73, 95% CI 0.61-0.89).^{2,3} Adverse events of grade 3 or higher occurred in 48% of the

Editor's Choice

New Programs

patients receiving enzalutamide, as compared with 27% of those receiving placebo.³ Common any-grade adverse events with enzalutamide included fatigue (46% vs. 22%), musculoskeletal events (34% vs. 23%), fracture (18% vs 6%), hypertension (18% vs. 6%) and falls (18% vs. 5%).³

Head and Neck

Capecitabine for Recurrent or Metastatic Squamous Cell Cancer of the Head and Neck (HNAVCAP) — The BC Cancer Head and Neck Tumour Group is implementing capecitabine as an oral alternative to weekly 5-fluorouracil/leucovorin therapy (HNAVFUFA) in patients with recurrent or metastatic head and neck squamous cell cancer (HNSCC). Two phase II studies demonstrated capecitabine to be active and well-tolerated in patients with previously-treated recurrent or metastatic HNSCC. ^{4,5} Capecitabine follows standard twice daily dosing on days 1-14 out of a 21 day cycle. Note that patients whose disease progresses on 5-fluorouracil are not eligible to receive capecitabine.

References

- 1. Pan-Canadian Oncology Drug Review (pCODR) Expert Review Committee (pERC). Final recommendation for enzalutamide (Xtandi®) for non-metastatic castrate-resistant prostate cancer. 26 March 2019.
- 2. Hussain M, Fizazi K, Saad F, et al. Enzalutamide in men with nonmetastatic, castration-resistant prostate cancer. *N Engl J Med* 2018; 378:2465-74. https://doi.org/10.1056/NEJMoa1800536
- 3. Sternberg CN, Fizazi K, Saad F, et al. Enzalutamide and survival in nonmetastatic, castration-resistant prostate cancer. *N Engl J Med* 2020; 382:2197-2206. https://doi.org/10.1056/NEJMoa2003892
- Martinez-Trufero J, Isla D, Adansa JC, et al. Phase II study of capecitabine as palliative treatment for patients with recurrent and metastatic squamous head and neck cancer after previous platinum-based treatment. Br J Cancer 2010;102:1687–1691. https://doi.org/10.1038/sj.bjc.6605697
- 5. Péron J, Poupart M, Ceruse P, et al. Efficacy and safety of capecitabine in heavily pretreated recurrent/metastatic head and neck squamous cell carcinoma. *Anti-Cancer Drugs* 2012;23:1107–1111. https://doi.org/10.1097/CAD.0b013e328358d226

Update: Influenza Vaccine Recommendations

The **BC Cancer Influenza Vaccine Recommendations for Adults with Cancer** are available on the BC Cancer website in the <u>Supportive Care</u> section of the Cancer Management Guidelines and on the <u>Immunotherapy</u> and <u>Supportive Care</u> pages in the Chemotherapy Protocols section.

Key updates for the 2020-2021 flu season include:

- · All patients should be offered an age-appropriate inactivated influenza vaccine
 - o The standard-dose inactivated influenza vaccine is indicated for all adults and is publicly funded in BC
 - The high-dose inactivated influenza vaccine is Health Canada-approved for use in adults 65 years of age and older; in BC it is publicly funded only for adults 65 years of age and older living in long term care or assisted living facilities
 - o Currently there is not enough information to recommend the high-dose over the standard-dose vaccine in the general oncology population
- In patients receiving the vaccine *before starting active chemotherapy,* the vaccine should preferably be administered 2 weeks or longer before the first round of chemotherapy (no later than 2 days prior to starting chemotherapy)
- Specific recommendations for patients receiving rituximab therapy have been added
- Patients receiving a CTLA-4 inhibitor (alone or in combination with a PD-1 or PD-L1 inhibitor) should not receive any vaccine within 4-6 weeks of starting treatment, and vaccination should be delayed for 4-6 weeks after the last dose of CTLA-4 inhibitor

Cancer Drug Manual[©]

All BC Cancer Drug Manual[©] documents can be accessed from the <u>Cancer Drug Manual</u>[©] home page on the BC Cancer website.

Revised Documents

Highlights of key changes are listed below:

Doxorubicin Pegylated Liposomal Chemotherapy Preparation and Stability Chart

Added Taro formulation as new brand

Palbociclib Monograph, Patient Handout (capsule) and Patient Handout (tablet)

Side Effects: added interstitial lung disease/pneumonitis to table

Patient Handouts: added lung problems to See Your Doctor or Get Emergency Help bullets

Ribociclib Monograph

Side Effects: added interstitial lung disease/pneumonitis to table

Benefit Drug List

New Programs

Effective 01 October 2020, the following new treatment programs have been added to the BC Cancer Benefit Drug List:

Protocol Title	Protocol Code	Benefit Status
Treatment of Non-Metastatic Castration-Resistant Prostate Cancer using Enzalutamide	UGUNMPENZ	Restricted
Treatment of Recurrent or Metastatic Squamous Cell Cancer of the Head and Neck with Capecitabine	HNAVCAP	Class I

Revised Programs

Effective 01 October 2020, the following treatment programs no longer require Compassionate Access Program (CAP) approval and have been transferred to Class I status on the BC Cancer Benefit Drug List:

Protocol Title	Protocol Code	Benefit Status
Treatment of Relapsed or Refractory Hodgkin Lymphoma using Pembrolizumab	LYPEM	Class I (Previously Restricted)
Treatment of Relapsed or Refractory Hodgkin Lymphoma using 6-Weekly Pembrolizumab	LYPEM6	Class I (Previously Restricted)

Highlights of New & Revised Protocols, PPPOs 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, with document revisions indicated in the respective columns. Protocol codes for treatment requiring BC Cancer Compassionate Access Program approval are prefixed with the letter **U**.

NEW Protocols, PPPOs and Patient Handouts (new documents checked ☑)				
Code	Protocol Title	Protocol	PPPO	Handout
UGUNMPENZ	Treatment of Non-Metastatic Castration- Resistant Prostate Cancer using Enzalutamide	\square		
HNAVCAP	Treatment of Recurrent or Metastatic Squamous Cell Cancer of the Head and Neck with Capecitabine	V	V	I

REVISED Protocols, PPPOs and Patient Handouts (revisions in respective columns)				
Code	Protocol Title	Protocol	PPPO	Handout
BR Breast				
BRAVABR	Palliative Therapy for Metastatic Breast Cancer using Paclitaxel NAB (ABRAXANE)	Dose Modifications clarified (hepatic and renal)		
BRAVPTRAD	Palliative Therapy for Metastatic Breast Cancer using Pertuzumab, Trastuzumab (HERCEPTIN) and Docetaxel as First-Line Treatment for Advanced Breast Cancer		Minor typo corrected	
GI Gastroin	testinal			
GIAJCAPOX	Adjuvant Combination Chemotherapy for Stage III and Stage IIB Colon Cancer using Oxaliplatin and Capecitabine	Number of treatment cycles and oxaliplatin bag size clarified	Checkbox for optional fluids added (D5W infused with oxaliplatin to reduce phlebitis)	Number of treatment cycles clarified
GIAJFFOX	Adjuvant Combination Chemotherapy for Stage III and Stage IIB Colon Cancer using Oxaliplatin, Fluorouracil and Leucovorin	Number of treatment cycles clarified		Number of treatment cycles clarified
GICAPOX	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer using Oxaliplatin and Capecitabine	Oxaliplatin bag size clarified	Checkbox for optional fluids added (D5W infused with oxaliplatin to reduce phlebitis)	

REVISED Protocols, PPPOs and Patient Handouts (revisions in respective columns)				
Code	Protocol Title	Protocol	PPPO	Handout
GICOXB	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer using Oxaliplatin, Bevacizumab and Capecitabine	Oxaliplatin bag size clarified	Checkbox for optional fluids added (D5W infused with oxaliplatin to reduce phlebitis)	
GIEFFOXRT	Adjuvant Combination Chemotherapy for Stage III and Stage IIB Colon Cancer using Oxaliplatin, Fluorouracil and Leucovorin	Oxaliplatin bag size clarified and leucovorin dosing clarified		
UGIFFIRPAN	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer using Irinotecan, Fluorouracil, Leucovorin and Panitumumab		Hypersensitivity tray removed	
GIGAJCOX	Adjuvant Chemotherapy in Gastric Cancer Patients with D2 Resection (Node-Negative) or Ineligible-for-Adjuvant Chemoradiation using Oxaliplatin and Capecitabine	Oxaliplatin bag size clarified	Checkbox for optional fluids added (D5W infused with oxaliplatin to reduce phlebitis)	
GIGAVCOX	Palliative Treatment of Metastatic or Locally Advanced Gastric, Gastroesophageal Junction or Esophageal Adenocarcinoma using Capecitabine and Oxaliplatin	Oxaliplatin bag size clarified	Checkbox for optional fluids added (D5W infused with oxaliplatin to reduce phlebitis)	
GIGAVCOXT	Palliative Treatment of Metastatic or Locally Advanced Gastric, Gastroesophageal Junction or Esophageal Adenocarcinoma using Capecitabine, Oxaliplatin and Trastuzumab	Oxaliplatin bag size clarified	Checkbox for optional fluids added (D5W infused with oxaliplatin to reduce phlebitis); minor reformatting (location of capecitabine and acetaminophen within PPPO)	
UGILEN	First-Line Therapy of Advanced Hepatocellular Carcinoma using Lenvatinib		Dispensing supply updated	
GIPGEMABR	First-Line Treatment of Locally Advanced and Metastatic Pancreatic Cancer with Paclitaxel NAB (ABRAXANE) and Gemcitabine	Eligibility updated and Dose Modifications clarified (hepatic and renal)		
GIRAJCOX	Adjuvant Combination Chemotherapy for Stage III Rectal Cancer using Oxaliplatin and Capecitabine	Oxaliplatin bag size clarified	Checkbox for optional fluids added (D5W infused with oxaliplatin to reduce phlebitis)	

REVISED Protocols, PPPOs and Patient Handouts (revisions in respective columns)				
Code	Protocol Title	Protocol	PPPO	Handout
GO Gynecol	ogy			
GOOVBEVG	Treatment of Platinum-Resistant Epithelial Ovarian Cancer with Bevacizumab and Gemcitabine		Hypersensitivity tray removed	
GOOVBEVLD	Treatment of Platinum-Resistant Epithelial Ovarian Cancer with Bevacizumab and Doxorubicin Pegylated Liposomal (CAELYX)		Hypersensitivity tray removed	
GU Genitou	rinary			
UGUAVPEM	Treatment of Locally Advanced or Metastatic Urothelial Carcinoma using Pembrolizumab	Minor typo corrected	Minor typo corrected	
UGUAVPEM6	Treatment of Locally Advanced or Metastatic Urothelial Carcinoma using 6-Weekly Pembrolizumab	Minor typo corrected	Tests updated	
GUNAJPG	Therapy for Urothelial Carcinoma using Cisplatin and Gemcitabine		Gemcitabine bag size updated	
UGUPABI	Palliative Therapy for Metastatic Castration- Resistant Prostate Cancer using Abiraterone and Prednisone	Eligibility, Tests and Contact Physician updated; funding algorithm added	Tests updated	
UGUPAPA	Treatment of Non-Metastatic Castration- Resistant Prostate Cancer using Apalutamide	Eligibility and funding algorithm updated		
GUPCABA	Palliative Therapy for Metastatic Castration- Resistant Prostate Cancer using Cabazitaxel and Prednisone	Eligibility and funding algorithm updated		
UGUPENZ	Palliative Therapy for Metastatic Castration- Resistant Prostate Cancer using Enzalutamide	Eligibility and funding algorithm updated; Dose Modifications added	Dose Modifications added	
HN Head an	d Neck			
UHNAVNIV	Palliative Therapy for Unresectable, Platinum- Refractory, Recurrent or Metastatic Squamous Cell Cancer of the Head and Neck using Nivolumab		Hypersensitivity tray removed	
UHNAVNIV4	Palliative Therapy for Unresectable, Platinum- Refractory, Recurrent or Metastatic Squamous Cell Cancer of the Head and Neck using 4-Weekly Nivolumab		Hypersensitivity tray removed	
HNNAVPG	Treatment of Locoregionally Recurrent and/or Metastatic Nasopharyngeal Cancer with Platinum and Gemcitabine		Antiemetics clarified	

REVISED Protocols, PPPOs and Patient Handouts (revisions in respective columns)				
Code	Protocol Title	Protocol	PPPO	Handout
LY Lymphon	na			
LYCODOXMR	Treatment of Burkitt Lymphoma and Leukemia (ALL-L3) with Cyclophosphamide, Vincristine, Doxorubicin, Methotrexate, Leucovorin (CODOX-M) and Rituximab	Methotrexate levels clarified	Methotrexate levels clarified	
⊎LYPEM	Treatment of Relapsed or Refractory Hodgkin Lymphoma using Pembrolizumab	Protocol Code (U removed), Eligibility and Exclusions revised	CAP requirement and U in Protocol Code removed; hypersensitivity tray removed	Protocol Code revised (U removed)
⊎ LYPEM6	Treatment of Relapsed or Refractory Hodgkin Lymphoma using 6-Weekly Pembrolizumab	Protocol Code (U removed), Eligibility and Exclusions revised	CAP requirement and U in Protocol Code removed; hypersensitivity tray removed	Protocol Code revised (U removed)
SM Skin and	Melanoma			
SMAVFIPI	First-Line Treatment of Unresectable or Metastatic Melanoma using Ipilimumab		Hypersensitivity tray removed	
SMAVIPI	Treatment of Unresectable or Metastatic Melanoma using Ipilimumab		Hypersensitivity tray removed	
SMAVPEM	Treatment of Unresectable or Metastatic Melanoma using Pembrolizumab		Hypersensitivity tray removed	
SMAVPEM6	Treatment of Unresectable or Metastatic Melanoma using 6-Weekly Pembrolizumab		Hypersensitivity tray removed	
SMMCCPE	Treatment of Recurrent or Metastatic Merkel Cell Carcinoma (MCC) with Cisplatin and Etoposide		Tests clarified	

Resources and Contact Information			
Resource	Phone	Email / Toll Free / Fax	
Systemic Therapy Update: www.bccancer.	oc.ca/health-professionals/clinical-resources/s	systemic-therapy/systemic-therapy-update	
Systemic Therapy Update Editor	604-877-6000 x 672649	bulletin@bccancer.bc.ca	
Oncology Drug Information Cancer Drug Manual Editor Pharmacy Oncology Certification Nurse Educators	604-877-6275 250-519-5500 x 693742 250-712-3900 x 686820 604-877-6000 x 672638	druginfo@bccancer.bc.ca nbadry@bccancer.bc.ca rxchemocert@bccancer.bc.ca nursinged@bccancer.bc.ca	
CAP – Compassionate Access Program	604-877-6277	cap bcca@bccancer.bc.ca fax 604-708-2026	
OSCAR – Online System for Cancer Drugs Adjudication and Reimbursement	888-355-0355	oscar@bccancer.bc.ca fax 604-708-2051	
Manufacturer Patient Assistance Programs: www.bccancer.bc.ca/health-professionals/clinical-resources/systemic-therapy/			
Library/Cancer Information	604-675-8003	toll free 888-675-8001 x 8003 requests@bccancer.bc.ca	
Library Document Delivery	604-675-8002	requests@bccancer.bc.ca	
Pharmacy Professional Practice Professional Practice, Nursing Provincial Systemic Therapy Program	604-877-6000 x 672247 604-877-6000 x 672623 604-877-6000 x 672247	mlin@bccancer.bc.ca BCCancerPPNAdmin@ehcnet.phsa.ca mlin@bccancer.bc.ca	
BC Cancer – Abbotsford BC Cancer – Kelowna BC Cancer – Prince George BC Cancer – Surrey BC Cancer – Vancouver BC Cancer – Victoria	604-851-4710 250-712-3900 250-645-7300 604-930-2098 604-877-6000 250-519-5500	toll free 877-547-3777 toll free 888-563-7773 toll free 855-775-7300 toll free 800-523-2885 toll free 800-663-3333 toll free 800-670-3322	
Community Oncology Network (CON) sites: To update your contact information, please contact: <u>bulletin@bccancer.bc.ca</u>			

Editorial Review Board

Anne Dar Santos, BScPharm, PharmD (Editor) Fatima Ladha, BScPharm (Assistant Editor) Mario de Lemos, PharmD, MSc(Oncol) Jeevan Dosanjh, RN, BScN Alina Gerrie, MD, MPH, FRCPC Alison Pow, BScPharm