

Systemic Therapy Update

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For Health Professionals Who Care for Cancer Patients

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New Programs

The BC Cancer Provincial Systemic Therapy Program has approved the following new treatment programs effective 01 December 2021. Full details of all treatment programs are available in the Chemotherapy Protocols section of the BC Cancer website.

Gynecologic

Niraparib for Maintenance of Newly Diagnosed Platinum-Responsive Ovarian Cancer (UGOOVFNIRM) —

The BC Cancer Gynecologic Oncology Tumour Group is introducing niraparib for the maintenance treatment of patients with newly diagnosed platinum-responsive epithelial ovarian, fallopian tube or peritoneal carcinoma. Niraparib is a PARP inhibitor with activity irrespective of tumour BRCA mutation status. Niraparib maintenance treatment must be initiated within 12 weeks of completing at least six cycles of first-line platinum chemotherapy. BC Cancer Compassionate Access Program (CAP) approval is required. Patients are eligible to receive only one line of PARP inhibitor treatment – niraparib using UGOOVFNIRM or UGOOVNIRAM, or olaparib. Olaparib is indicated for patients with BRCA 1 or 2 mutations using GOOVFOLAM or GOOVOLAPM; these protocols no longer require BC Cancer CAP approval.

Approval for niraparib in newly diagnosed patients responding to first-line platinum-based chemotherapy comes from the randomized, placebo-controlled, phase III PRIMA trial.^{1,2} In both the overall study

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population and the BRCA mutation subgroup, the primary endpoint of median progression-free survival (mPFS) was significantly longer in the niraparib group (overall population: 13.8 months vs. 8.2 months, HR 0.62, 95% CI 0.50-0.76; BRCA subgroup: 22.1 months vs. 10.9 months, HR 0.40, 95% CI 0.27-0.62). The most common adverse events (AEs) of grade 3 or higher occurred more frequently in the niraparib group, including anemia (31.0% vs. 1.6%), thrombocytopenia (28.7% vs. 0.4%) and neutropenia (12.8% vs. 1.2%).

Niraparib for Maintenance of <u>Relapsed</u> Platinum-Sensitive and Platinum-Responsive Ovarian Cancer (UGOOVNIRAM) — The BC Cancer Gynecologic Oncology Tumour Group is also introducing niraparib for the maintenance treatment of patients with relapsed platinum-sensitive or platinum-responsive epithelial ovarian, fallopian tube or peritoneal carcinoma, irrespective of tumour BRCA mutation status. Niraparib maintenance treatment must be initiated within 8 to 12 weeks of completing the last dose of platinum chemotherapy retreatment. BC Cancer CAP approval is required. Patients are eligible to receive only one line of PARP inhibitor treatment, as outlined in the UGOOVFNIRM section above.

Approval for maintenance niraparib – following two or more prior lines of platinum chemotherapy – comes from the randomized, placebo-controlled, phase III NOVA trial.^{3,4} In both the cohort with a germline BRCA mutation and the non-BRCA cohort, the primary endpoint of mPFS was significantly longer in the niraparib group (BRCA cohort: 21.0 vs. 5.5 months, HR 0.27, 95% CI 0.17-0.41; non-BRCA cohort: 9.3 months vs. 3.9 months, HR 0.45, 95% CI 0.34-0.61). The most common grade 3 or 4 AEs reported in the niraparib group were thrombocytopenia (33.8% vs. 0.6%), anemia (25.3% vs. 0%) and neutropenia (19.6% vs. 1.7%).

Genitourinary

Apalutamide for Metastatic Castration-Sensitive Prostate Cancer (UGUMCSPAPA) — The BC Cancer Genitourinary Tumour Group is implementing apalutamide for patients with metastatic castration-sensitive prostate cancer (mCSPC). Patients with mCSPC are eligible for this treatment program if they are chemotherapy naïve or have received prior docetaxel-containing chemotherapy; in addition, they must have received no prior androgen deprivation therapy (ADT), or received ADT for less than 6 months in the setting of mCSPC. Patients without orchiectomy should be maintained on ADT with LHRH agonist or antagonist while on this treatment program. BC Cancer CAP approval is required.

Approval for this treatment program is based on the phase III TITAN trial, which randomized patients to receive either apalutamide or placebo; both groups received ADT.^{5,6} At the 24-month interim analysis, significantly more patients achieved radiographic progression-free survival (rPFS) in the apalutamide group (68.2% vs. 47.5%, HR 0.48, 95% CI 0.39-0.60). Overall survival (OS) at the interim analysis was also greater with apalutamide (82.4% vs. 73.5%, HR 0.67, 95% CI 0.51-0.89). Frequencies of grade 3 or 4 AEs did not differ substantially between the apalutamide and placebo groups (42.2% vs. 40.8%), the most common being hypertension (8.4% vs. 9.1%) and rash (6.3% vs. 0.6%).

Enzalutamide for Metastatic Castration-Sensitive Prostate Cancer (UGUMCSPENZ) — The BC Cancer Genitourinary Tumour Group is also implementing enzalutamide for patients with mCSPC. Patients with mCSPC are eligible for this treatment program if they are chemotherapy naïve or have received prior docetaxel-containing chemotherapy; in addition, they must have received no prior ADT, or received ADT for less than 6 months in the setting of mCSPC. Patients without orchiectomy should be maintained on ADT with LHRH agonist or antagonist while on this treatment program. BC Cancer CAP approval is required.

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Approval for enzalutamide in this treatment setting is based two phase III trials: the placebo-controlled ARCHES trial, and the ENZAMET trial comparing enzalutamide with a first-generation non-steroidal antiandrogen (NSAA).⁷⁻⁹ All patients in both trials received ADT. In ARCHES, enzalutamide was associated with a longer median rPFS when compared to placebo (not reached vs. 19.0 months, HR 0.39, 95% CI 0.30-0.50). ENZAMET demonstrated a significant improvement in OS (HR 0.67, 95% CI 0.52-0.86); the Kaplan-Meier estimates for three-year OS were 80% in the enzalutamide group and 72% in the NSAA group. More patients in the enzalutamide group had grade 3 or higher AEs (57% vs. 43%), including hypertension (8% vs. 4%), neutropenia (6% vs. 3%) and fatigue (6% vs. 1%).

Head and Neck

6-Weekly Pembrolizumab for First-Line Treatment of Head and Neck Carcinoma (UHNAVPMBF6) — The BC Cancer Head and Neck Tumour Group is adding a 6-weekly dosing option for pembrolizumab monotherapy when used in the first-line treatment of advanced squamous cell carcinoma of the head and neck. ¹⁰⁻¹³ Patients switching from the existing 3-weekly dosing schedule to the 6-weekly dosing schedule should receive the first 6-weekly dose on the day they are due for their next 3-weekly dose. New BC Cancer CAP approval is not required to switch between UHNAVPMBF and UHNAVPMBF6. Treatment may be continued for a maximum of two years, including pembrolizumab doses given as UHNAVPMBF and UHNAVPMBF6.

Pembrolizumab dosing options in this setting now include:

Protocols	Dosing Schedules
UHNAVPMBF	Pembrolizumab 2 mg/kg IV every 3 weeks (maximum 200 mg)
UHNAVPMBF6 (new)	Pembrolizumab 4 mg/kg IV every 6 weeks (maximum 400 mg)

6-Weekly Pembrolizumab for Maintenance Treatment of Head and Neck Carcinoma (HNAVPMBM6) -

The BC Cancer Head and Neck Tumour Group is adding a 6-weekly dosing option for pembrolizumab monotherapy when used in the maintenance treatment of advanced squamous cell carcinoma of the head and neck.¹⁰⁻¹³ Patients switching from the existing 3-weekly dosing schedule to the 6-weekly dosing schedule should receive the first 6-weekly dose on the day they are due for their next 3-weekly dose. BC Cancer CAP approval is not required to switch between HNAVPMBM and HNAVPMBM6. Treatment may be continued for a maximum of two years, including pembrolizumab doses given with chemotherapy (UHNAVPFPMB or UHNAVPCPMB), HNAVPMBM and HNAVPMBM6.

Pembrolizumab dosing options in the maintenance setting now include:

Protocols Dosing Schedules	
HNAVPMBM	Pembrolizumab 2 mg/kg IV every 3 weeks (maximum 200 mg)
HNAVPMBM6 (new)	Pembrolizumab 4 mg/kg IV every 6 weeks (maximum 400 mg)

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- 13. Lala M, Li M, Sinha V, et al. A six-weekly (Q6W) dosing schedule for pembrolizumab based on an exposure-response (ER) evaluation using modeling and simulation. Poster at: 2018 American Society of Clinical Oncology (ASCO) Annual Meeting; 2018 Jun 1-5; Chicago, IL.

Provincial Systemic Therapy Program

All policies and procedures are on the Shared Health Organizations Portal (SHOP) BC Cancer page.

Updated: Selecting Patient Medication Handouts

Policy III-160: **Selecting Patient Medication Handouts**, now reclassified as **Protocol III-160**, has been updated to include new BC Cancer formatting and additional links to the Patient Education Resources documents. This protocol helps guide health professionals to select patient handouts from various resources/databases when they are not available in the BC Cancer Drug Manual[©] on the BC Cancer website.

Cancer Drug Manual[©]

All documents are available in the Cancer Drug Manual[©] on the BC Cancer website.

Translated Documents

The **Fluorouracil INFUSOR Patient Handout (Your INFUSOR – A Guide for Patients)** has been translated and made available in Simplified Chinese, Traditional Chinese, French and Punjabi.

Cancer Drug Manual®

New Documents

Note that the following drug is <u>not</u> a BC Cancer Benefit Drug and requires application to the BC Cancer Compassionate Access Program (CAP). The corresponding Interim Monograph and Patient Handout are made available for reference only.

The **Brigatinib Interim Monograph** and **Patient Handout** have been developed with expert review provided by Dr. Sophie Sun, medical oncologist of the BC Cancer Lung Tumour Group. Brigatinib is a broad spectrum tyrosine kinase inhibitor used in the treatment of non-small cell lung cancer. The usual dose is 90 mg orally once daily for 7 days, followed by 180 mg once daily thereafter.

Highlights from these documents include:

- fatigue, diarrhea and nausea are frequently reported side effects
- bradycardia, sinus bradycardia, hypertension and prolongation of the PR interval may occur; monitor heart rate and blood pressure regularly
- pulmonary adverse reactions including dyspnea, cough, hypoxia, pneumonia and/or pneumonitis may occur early in treatment; monitor for symptoms particularly during the first 7 days

Brigatinib has been added to the **Auxiliary Label List** and has been evaluated for the **BC Cancer Hazardous Drug List**.

Revised Documents

Cladribine Chemotherapy Preparation and Stability Chart

added GMP as new brand

Niraparib Monograph

Dosage Guidelines: added BC Cancer protocols to references and bolded and italicized BC Cancer usual dose; updated dosing in hepatic failure

Pamidronate Monograph

Dosage Guidelines: deleted reference to SCHYPCAL as this protocol has been retired at BC Cancer

Treosulfan Chemotherapy Preparation and Stability Chart

added Medexus as new brand

Zoledronic Acid Monograph

Dosage Guidelines: deleted reference to SCHYPCAL as this protocol has been retired at BC Cancer

Benefit Drug List

New Programs

The following new treatment programs have been added to the BC Cancer <u>Benefit Drug List</u> effective 01 December 2021:

Protocol Title	Protocol Code	Benefit Status
Maintenance Treatment of Newly Diagnosed Platinum-Responsive Epithelial Ovarian Cancer using Niraparib	UGOOVFNIRM	Restricted
Maintenance Treatment of Relapsed Platinum-Sensitive and -Responsive Epithelial Ovarian Cancer using Niraparib	UGOOVNIRAM	Restricted
Treatment of Metastatic Castration-Sensitive Prostate Cancer using Apalutamide	UGUMCSPAPA	Restricted
Therapy for Metastatic Castration-Sensitive Prostate Cancer using Enzalutamide	UGUMCSPENZ	Restricted
First-Line Treatment of Advanced Squamous Cell Carcinoma of the Head and Neck using 6-Weekly Pembrolizumab	UHNAVPMBF6	Restricted
Maintenance Treatment of Advanced Squamous Cell Carcinoma of the Head and Neck using 6-Weekly Pembrolizumab	НПА ГРИВИ В В В В В В В В В В В В В В В В В В	Class I

Revised Programs

The following treatment programs have been revised on the BC Cancer <u>Benefit Drug List</u> effective 01 December 2021:

Protocol Title	Protocol Code	Benefit Status
Maintenance Treatment of Newly Diagnosed BRCA-Mutated Platinum-Responsive Epithelial Ovarian Cancer using Olaparib	GOOVFOLAM	Class I (previously Restricted)
Maintenance Treatment of Relapsed, BRCA-Mutated, Platinum-Sensitive and -Responsive Epithelial Ovarian Cancer using Olaparib	GOOVOLAPM	Class I (previously Restricted)
Palliative Therapy for Unresectable, Platinum-Refractory, Recurrent or Metastatic Squamous Cell Cancer of the Head and Neck using Nivolumab	HNAVNIV	Class I (previously Restricted)
Palliative Therapy for Unresectable, Platinum-Refractory, Recurrent or Metastatic Squamous Cell Cancer of the Head and Neck using 4-Weekly Nivolumab	HNAVNIV4	Class I (previously Restricted)
Treatment of Chronic Myeloid Leukemia using Nilotinib	LKCMLN	Class I (previously Restricted)
Treatment of Cutaneous T-Cell Lymphoma (Sézary Syndrome) with Extracorporeal Photopheresis	LYMFECP	Class I (previously Restricted)

NEW Protocols, PPPOs and Patient Handouts (new documents checked ☑)				
Protocol Code	Protocol Title	Protocol	PPPO	Handout
UGOOVFNIRM	Maintenance Treatment of Newly Diagnosed Platinum-Responsive Epithelial Ovarian Cancer using Niraparib	$\overline{\checkmark}$	I	
UGOOVNIRAM	Maintenance Treatment of Relapsed Platinum- Sensitive and -Responsive Epithelial Ovarian Cancer using Niraparib	V	Ø	
UGUMCSPAPA	Treatment of Metastatic Castration-Sensitive Prostate Cancer using Apalutamide	Ø	Ø	
UGUMCSPENZ	Therapy for Metastatic Castration-Sensitive Prostate Cancer using Enzalutamide	Ø	\square	
UHNAVPMBF6	First-Line Treatment of Advanced Squamous Cell Carcinoma of the Head and Neck using 6-Weekly Pembrolizumab	V	I	
HNAVPMBM6	Maintenance Treatment of Advanced Squamous Cell Carcinoma of the Head and Neck using 6-Weekly Pembrolizumab	V	V	

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 (CAP) approval are prefixed with the letter **U**.

REVISED Protocols, PPPOs and Patient Handouts (revisions in respective columns)				
Protocol Code	Protocol Title	Protocol	PPPO	Handout
BR Breast				
BRAVCAP	Therapy of Metastatic Breast Cancer using Capecitabine	Treatment revised	Default dosing option revised	
BRAVPTRAD	Palliative Therapy for Metastatic Breast Cancer using Pertuzumab, Trastuzumab (HERCEPTIN) and Docetaxel as First-Line Treatment for Advanced Breast Cancer	Treatment, Dose Modifications and References revised	Q4weekly dosing option added	
BRAVPTRAT	Palliative Therapy for Metastatic Breast Cancer using Pertuzumab, Trastuzumab (HERCEPTIN) and Paclitaxel as First-Line Treatment for Advanced Breast Cancer	Treatment, Dose Modifications and References revised	Q4weekly dosing option added	
BRAVTCAP	Palliative Therapy for Metastatic Breast Cancer using Trastuzumab and Capecitabine	Treatment revised	Default dosing option revised	
BRAVTR	Palliative Therapy for Metastatic Breast Cancer using Trastuzumab	Dose Modifications revised		

REVISED Protocols, PPPOs and Patient Handouts (revisions in respective columns)				
Protocol Code	Protocol Title	Protocol	PPPO	Handout
GI Gastrointe	estinal			
GIRALT	Palliative Chemotherapy for Metastatic Colorectal Cancer using Raltitrexed in Patients with Previous Fluorouracil Toxicity	Contact Physician revised; Eligibility and treatment duration clarified		
GO Gynecolo	gic			
⊎GOOVFOLAM	Maintenance Treatment of Newly Diagnosed BRCA- Mutated Platinum-Responsive Epithelial Ovarian Cancer using Olaparib	Protocol Code revised (U removed); Eligibility revised (CAP requirement removed)	Protocol Code revised; CAP requirement removed	
⊎GOOVOLAPM	Maintenance Treatment of Relapsed, BRCA-Mutated, Platinum-Sensitive and -Responsive Epithelial Ovarian Cancer using Olaparib	Protocol Code revised (U removed); Eligibility revised (CAP requirement removed)	Protocol Code revised; CAP requirement removed	
GU Genitouri	nary			
GUBGEMDOC	Intravesical Therapy for Non-Muscle Invasive Bladder Cancer using Gemcitabine and Docetaxel	Treatment and Precautions updated	Treatment clarified	
UGUPABI	Palliative Therapy for Metastatic Castration-Resistant Prostate Cancer using Abiraterone and Prednisone	Eligibility updated		
UGUPENZ	Palliative Therapy for Metastatic Castration-Resistant Prostate Cancer using Enzalutamide	Eligibility updated		
HN Head and	Neck			
⊎HNAVNIV	Palliative Therapy for Unresectable, Platinum- Refractory, Recurrent or Metastatic Squamous Cell Cancer of the Head and Neck using Nivolumab	Protocol Code revised (U removed); Eligibility revised (CAP requirement removed); Exclusions and Tests revised	Protocol Code revised; CAP requirement removed; Tests revised	Protocol Code revised
⊎HNAVNIV4	Palliative Therapy for Unresectable, Platinum- Refractory, Recurrent or Metastatic Squamous Cell Cancer of the Head and Neck using 4-Weekly Nivolumab	Protocol Code revised (U removed); Eligibility revised (CAP requirement removed); Exclusions and Tests revised	Protocol Code revised; CAP requirement removed; Tests revised	Protocol Code revised
UHNAVPCPMB	First-Line Treatment of Advanced Squamous Cell Carcinoma of the Head and Neck with Paclitaxel, Carboplatin and Pembrolizumab	Treatment updated		
UHNAVPFPMB	First-Line Treatment of Advanced Squamous Cell Carcinoma of the Head and Neck using Platinum, Fluorouracil and Pembrolizumab	Eligibility clarified; Treatment updated		

REVISED Protocols, PPPOs and Patient Handouts (revisions in respective columns)				
Protocol Code	Protocol Title	Protocol	PPPO	Handout
HN Head and	Neck (continued)			
UHNAVPMBF	First-Line Treatment of Advanced Squamous Cell Carcinoma of the Head and Neck with Pembrolizumab	Eligibility updated		
HNAVPMBM	Maintenance Treatment of Advanced Squamous Cell Carcinoma of the Head and Neck with Pembrolizumab	Eligibility and Treatment updated		
HNOTLEN	Therapy for Locally Recurrent or Metastatic, RAI- Refractory Differentiated Thyroid Cancer using Lenvatinib	Eligibility clarified; Tests revised	Tests revised	
LK Leukemia				
⊎LKCMLN	Treatment of Chronic Myeloid Leukemia using Nilotinib	Protocol Code revised (U removed); Eligibility revised (CAP requirement removed)	Protocol Code revised; CAP requirement removed	Institution name updated; Protocol Code revised
вмтмм0301	Conditioning Therapy for Autologous Stem Cell Transplant using High-Dose Melphalan in the Treatment of Multiple Myeloma	Premedications and hydration revised		
LY Lymphoma	a			
⊎LYMFECP	Treatment of Cutaneous T-Cell Lymphoma (Sézary Syndrome) with Extracorporeal Photopheresis	Protocol Code revised (U removed); Eligibility revised (CAP requirement removed); Contact Physician and References revised		
MY Myeloma				
UMYDARBD	Treatment of Relapsed and Refractory Multiple Myeloma with Daratumumab in Combination with Bortezomib and Dexamethasone with or without Cyclophosphamide	Eligibility, Exclusions and treatment cycle ordering clarified	Return Appointment Orders revised PPPO Cycle 2+	
UMYDARLD	Treatment of Relapsed and Refractory Multiple Myeloma with Daratumumab in Combination with Lenalidomide and Dexamethasone	Eligibility, Exclusions and treatment cycle ordering clarified	Return Appointment Orders revised PPPO Cycle 2+	
МҮРАМ	Treatment of Multiple Myeloma with Pamidronate	Reference to SCHYPCAL removed		
SC Supportive Care				
SCPAINLI	Extreme Pain Therapy using Parenteral Lidocaine	Tests revised		

Resources and Contact Information				
Resource	Phone	Email / Toll Free / Fax		
Systemic Therapy Update: www.bccancer	.bc.ca/health-professionals/cl	inical-resources/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	: http://www.bccancer.bc.c	a/mpap		
Library/Cancer Information	604-675-8003	requests@bccancer.bc.ca toll free 888-675-8001 x 8003		
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>				

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