

Systemic Therapy Update

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For Health Professionals Who Care for People with Cancer

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Editor's Choice

New Programs

BC Cancer Provincial Systemic Therapy has approved the following new treatment programs effective 01 March 2025. Full details of all treatment programs are available in the Chemotherapy Protocols section of the BC Cancer website.

Gastrointestinal

First-Line Palliative Treatment of Advanced Biliary Tract Cancer using Pembrolizumab, Gemcitabine and Platinum (GIAVPEMPG) – The BC Cancer Gastrointestinal Tumour Group is introducing pembrolizumab in combination with gemcitabine and platinum as an alternative treatment for patients with metastatic or unresectable biliary tract cancer. Patients are eligible if they have not received prior systemic treatment in the advanced setting or experience a recurrence a minimum of 6 months after prior adjuvant treatment. Currently the standard therapy for these patients is durvalumab in combination with gemcitabine and platinum.

Editor's Choice

The new treatment is supported by evidence from a phase III trial, KEYNOTE-966, showing improved overall survival compared to gemcitabine-based chemotherapy alone.^{1,2} The combination regimen is associated with manageable toxicities consistent with the known safety profile of pembrolizumab, gemcitabine and platinums.¹

Genitourinary

Treatment of Metastatic Castration-Resistant Prostate Cancer using Niraparib-Abiraterone and Prednisone (UGUPAVNABI) – The BC Cancer Genitourinary Tumour Group is introducing the combination product niraparib-abiraterone (AKEEGA) and prednisone for patients with metastatic castration-resistant prostate cancer (mCRPC) that have a deleterious germline and/or somatic *BRCA1* or *BRCA2* gene alteration. Patients are eligible if they have confirmed *BRCA1*/2 mutations and have not been treated with an androgen receptor pathway inhibitor for earlier stages of prostate cancer or a PARP inhibitor for mCRPC. BC Cancer Compassionate Access Program (CAP) approval is required prior to treatment.

This treatment is supported by evidence from a phase III trial, MAGNITUDE, showing improved radiographic progression free survival associated with the combination product with prednisone compared to abiraterone only with prednisone.^{3,4} This new treatment is associated with manageable toxicities consistent with the known safety profile of niraparib, abiraterone and prednisone.

Lymphoma

Treatment of Lymphoma using Glofitamab (ULYOGLOFIT) – The BC Cancer Lymphoma Tumour Group is introducing glofitamab for the treatment of relapsed or refractory B-cell lymphoma. Patients are eligible if they have received two or more lines of systemic therapy, including CAR T-cell therapy, unless unable to receive. BC Cancer Compassionate Access Program (CAP) approval is required prior to treatment.

Glofitamab is a bispecific T-cell engager that simultaneously binds to CD20 on B-cells and CD3 receptors on T-cells. Evidence from an ongoing phase I/II trial indicates that treatment with glofitamab may result in significant improvements in overall survival and progression free survival.^{5,6} Glofitamab was also associated with a clinically meaningful complete response rate and durable response.⁶ Glofitamab is associated with cytokine release syndrome (CRS), immune effector cell-associated neurotoxicity syndrome (ICANS), tumour flare, neutropenia, thrombocytopenia, lymphopenia and leukopenia. Patients are routinely pre-treated with obinutuzumab to mitigate CRS.

References:

- Kelley RK, Ueno M, Yoo C, et al; KEYNOTE-966 Investigators. Pembrolizumab in combination with gemcitabine and cisplatin compared with gemcitabine and cisplatin alone for patients with advanced biliary tract cancer (KEYNOTE-966): a randomized, double-blind, placebocontrolled phase 3 trial. Lancet 2023 Jun3;401(10391):1853-1865.
- 2. Pembrolizumab (Keytruda) CADTH Reimbursement Recommendation. Canadian Journal of Health Technologies Jul 2024; 4(7): 1-26.
- 3. Chi KN, Rathkopf D, Smith MR, et al; MAGNITUDE Principal Investigators. Niraparib and abiraterone acetate for metastatic castration-resistant prostate cancer. J Clin Oncol. 2023 Jun 20;41(18):3339-3351.
- 4. Niraparib and Abiraterone Acetate (Akeega) CADTH Reimbursement Recommendation. Canadian Journal of Health Technologies. Feb 2024; 4(2):1-24.
- 5. Dickinson MJ, Carlo-Stella C, Morschhauser F, et al. Glofitamab for relapsed or refractory diffuse large b-cell lymphoma. N Engl J Med. 2022 Dec 15;387(24):2220-2231.
- 6. Glofitamab (Columvi) CADTH [Canada's Drug Agency (CDA-AMC)] Reimbursement Recommendation. Canadian Journal of Health Technologies Feb 2024; 4(2): 1-27.

Cancer Drug Manual[©]

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

New Documents

The Niraparib-Abiraterone Monograph and Patient Handout have been developed with expert review provided by Dr. Krista Noonan (medical oncologist, BC Cancer Genitourinary Tumour Group) and Megan Darbyshire (tumour group pharmacist, BC Cancer Provincial Pharmacy). Niraparib-abiraterone is a combination drug product containing niraparib (PARP inhibitor) and abiraterone (CYP17 enzyme inhibitor). The usual dose for the treatment of advanced prostate cancer is two tablets taken once daily on a continuous basis, providing niraparib 200 mg and abiraterone 1000 mg per day.

Highlights from these documents include:

- treatment-associated hypertension, hypokalemia, and fluid retention may worsen pre-existing cardiovascular disease; blood pressure should be adequately controlled prior to starting treatment
- hematologic toxicity mostly occurs during the first two months of treatment
- severe hepatotoxicity with marked increased in liver enzymes can occur with niraparib-abiraterone

Niraparib-abiraterone has been added to the Auxiliary Label List and evaluated for the BC Health Authorities Provincial Hazardous Drug List.

The **Glofitamab Monograph** and **Patient Handout** have been developed. Dr. Laurie Sehn (medical oncologist, BC Cancer Lymphoma Tumour Group) and Megan Darbyshire (tumour group pharmacist, BC Cancer Provincial Pharmacy) provided expert review. Glofitamab is a bispecific T-cell engager that simultaneously binds to CD20 on B cells and CD3 receptors on T-cells. Glofitamab is used in the treatment of B-cell lymphoma. Cycle 1 includes pre-treatment with obinutuzumab followed by a step-up dosing regimen given IV weekly for 2 weeks. For cycle 2 to 12, the usual dosing is 30 mg IV given on day 1 of a 21-day cycle.

Highlights from these documents include:

- cytokine release syndrome (CRS) commonly occurs; to mitigate the risk of CRS, glofitamab is initiated in a step-up dosing regimen
- *immune effector cell-associated neurotoxicity syndrome (ICANS)* has been reported; most events occur during cycle 1 and 2
- patients with bulky tumours near airways or a vital organ are at increased risk of tumour flare

Glofitamab has been added to the **Chemotherapy Preparation and Stability Chart** and has been evaluated for the **BC Health Authorities Provincial Hazardous Drug List.**

The **Dostarlimab Monograph** has been expanded and a **Patient Handout** has been developed. Expert review was provided by Megan Darbyshire and Robert Tillmanns (tumour group pharmacists, BC Cancer Provincial Pharmacy). All monograph sections have been reviewed and updated.

The following sections have been added or expanded:

Pharmacokinetics Special Precautions Dosage Guidelines Interactions Side Effects

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Dostarlimab is an active immune-checkpoint inhibitor targeting the PD-1 receptor on T cells. Dostarlimab is used in the treatment of endometrial cancer. The usual dose is 500 mg IV on day 1 of a 21-day cycle and follows BC Cancer Protocols UGOEAVDCAT and UGOEAVDPNT.

Highlights from these documents include:

- refer to BC Cancer protocol SCIMMUNE to manage immune-mediated adverse reactions
- infusion-related reactions are rare, but can be severe

Dostarlimab has been added to the **Chemotherapy Preparation and Stability Chart,** and **Extravasation Hazard Table.**

Revised Documents

Daunorubicin Monograph

Cautions: updated Carcinogenicity and Pregnancy sections

Side Effects paragraphs (cardiac toxicity): deleted "Dose Conversion Table for Anthracyclines" and replaced it with link to updated table in the CDM Appendix

Supply and Storage: updated to include current Canadian brands

Parenteral Administration table: updated 'direct intravenous' with link to Systemic Therapy Policy III-20 as per current template

Dosage Guidelines (Suggested maximum lifetime dose): updated per current product information

Daunorubicin-cytarabine liposome Monograph

Side Effects paragraphs (cardiotoxicity): included link to "Dose Conversion Table for Anthracyclines" in the CDM Appendix

Dexrazoxane Chemotherapy Preparation and Stability Chart

Product column: updated range of volumes for bag size selection

Doxorubicin Monograph

Cautions: updated Carcinogenicity, Fertility, and Pregnancy sections

Side Effects paragraphs (cardiac toxicity): deleted "Dose Conversion Table for Anthracyclines" and replaced it with link to updated table in the CDM Appendix

Doxorubicin pegylated liposomal Monograph

Side Effects paragraphs (cardiotoxicity): included link to "Dose Conversion Table for Anthracyclines" in the CDM Appendix

Supply and Storage: updated to include current Canadian brands

Parenteral Administration table: updated 'direct intravenous' with link to Systemic Therapy Policy III-20 as per current template

Dosage Guidelines (Suggested maximum lifetime dose): updated per current product information Dosage Guidelines (Concurrent radiation): updated per current protocol

Epirubicin Monograph

Cautions: updated Carcinogenicity, Fertility, and Pregnancy sections

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Side Effects paragraphs (cardiac toxicity): deleted "Dose Conversion Table for Anthracyclines" and replaced it with link to updated table in the CDM Appendix

Supply and Storage: updated to include current Canadian brands

Parenteral Administration table: updated 'direct intravenous' with link to Systemic Therapy Policy III-20 as per current template

Dosage Guidelines (Suggested maximum lifetime dose): updated per current product information

Idarubicin Monograph

Cautions: updated Mutagenicity, Fertility, Pregnancy, and Breastfeeding sections

Side Effects paragraphs (cardiac toxicity): deleted "Dose Conversion Table for Anthracyclines" and replaced it with link to updated table in the CDM Appendix

Supply and Storage: updated to include current Canadian brands

Parenteral Administration table: updated 'direct intravenous' with link to Systemic Therapy Policy III-20 as per current template

Mitoxantrone Monograph

Cautions: updated Mutagenicity, Fertility, Pregnancy, and Breastfeeding sections

Side Effects table (extravasation): deleted details from table and added cross reference to Side Effects paragraph instead

Side Effects paragraphs (cardiac toxicity): deleted "Dose Conversion Table for Anthracyclines" and replaced it with link to updated table in the CDM Appendix

Side Effects paragraphs (local tissue damage): added new paragraph to include details about extravasation (to support assigned extravasation hazard)

Supply and Storage: updated to include current Canadian brands

Paclitaxel NAB Chemotherapy Preparation and Stability Chart

Drug & Strength column: updated ABRAXANE® brand to include both Celgene and BMS as manufacturer (NOTE: packaging may indicate manufacturer as Celgene [old supply] or BMS [new supply]; products have the same DIN# and are otherwise the same)

Palbociclib Monograph

Supply and Storage: deleted the capsule formulation as no longer available in Canada

Retired Documents

The Palbociclib capsule Patient Handout has been retired.

Revised Dose Conversions for Anthracyclines Exposure

The dose conversions for cumulative exposure of anthracyclines and mitoxantrone have been revised based on the latest updates of the Children's Oncology Group (COG) Long-Term Follow-Up Guidelines,¹ which have adopted new data of long-term cardiotoxicity of anthracyclines and mitoxantrone.² The revised dose conversion is now available as a standalone table on the BC Cancer Drug Manual[®] Appendix webpage, as well as linked to the relevant individual monographs. The table provides fixed conversion factors rather than the previous ranges and includes information on liposomal anthracyclines products.

Cancer Drug Manual®

References

- 1. Children's Oncology Group. Long-term follow-up guidelines for survivors of childhood, adolescent, and young adult cancers. Version 6.0. Children's Oncology Group, October 2023. Available at: www.survivorshipguidelines.org. Accessed 21 March 2024.
- 2. Feijen EAM, Leisenring WM, Stratton KL, et al. Derivation of anthracycline and anthraquinone equivalence ratios to doxorubicin for late-onset cardiotoxicity. JAMA Oncol. 2019;5(6):864-71.

CDM Announcements

The NIOSH List of Hazardous Drugs in Healthcare Settings was updated December 2024. The **BC Provincial Hazardous Drug List** will be updated with relevant changes from the updated NIOSH List on March 1, 2025. The Hazardous Drug List can be accessed from the Cancer Drug Manual homepage - see <u>Hazardous Drug List</u>.

Continuing Education

Family Practice Oncology Network

The Family Practice Oncology Network (FPON) is pleased to announce a webinar session on Post-Breast Cancer Treatment Follow-up with Dr. Karen Gelmon, on Thursday 20 March 2025, from 8 to 9 am, as part of the Complimentary Accredited Webinar Series.

By the end of the session, participants will be able to:

- Cite post-breast cancer treatment surveillance
- Describe short-term side effect monitoring recommendations of patients on hormone therapy
- Discuss the late effects of breast cancer treatments

For more information and link to registration, visit:

https://ubccpd.ca/learn/learning-activities/course?eventtemplate=904-fpon-webinar-postbreast-cancer-treatment-followup-care

Benefit Drug List

New Programs

The following treatment programs have been added to the BC Cancer Benefit Drug List effective 01 March 2025:

Protocol Title	Protocol Code	Benefit Status
First-line Palliative Treatment of Advanced Biliary Tract Cancer using Pembrolizumab , Gemcitabine and Platinum	GIAVPEMPG	Class I
Treatment for Metastatic Castration-Resistant Prostate Cancer using Niraparib-Abiraterone and Prednisone	UGUPAVNABI	Restricted
Treatment of Lymphoma using Glofitamab	ULYOGLOFIT	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 (CAP) approval are prefixed with the letter **U.**

NEW Protocols, PPPOs and Patient Handouts (new documents checked ☑)				
Protocol Code	Protocol Title	Protocol	PPPO	Handout
GIAVPEMPG	First-line Palliative Treatment of Advanced Biliary Tract Cancer using Pembrolizumab, Gemcitabine and Platinum	$\overline{\checkmark}$	$\overline{\checkmark}$	
UGUPAVNABI	Treatment for Metastatic Castration-Resistant Prostate Cancer using Niraparib-abiraterone and prednisone		\square	
ULYOGLOFIT	Treatment of Lymphoma using Glofitamab	\square	\square	

REVISED Protocols, PPPOs and Patient Handouts (revisions in respective columns)				
Protocol Code	Protocol Title	Protocol	PPPO	Handout
BR Breast				
BRAVEVEX	Therapy for Advanced Breast Cancer Using Everolimus and Exemestane	Tests, dose modifications and precautions updated, dosing clarified	Tests updated	
GI Gastrointestinal				
GIAVDURPG	First-line Palliative Treatment of Advanced Biliary Tract Cancer using Durvalumab, Gemcitabine and Platinum	Eligibility updated, exclusion added		

REVISED Protocols, PPPOs and Patient Handouts (revisions in respective columns)					
Protocol Code	Protocol Title	Protocol	PPPO	Handout	
GU Genitouri	nary				
GUMCSPABI	Therapy for Metastatic Castration Sensitive Prostate Cancer using Abiraterone and Prednisone	Eligibility updated			
GUMCSPAPA	Treatment of Metastatic Castration Sensitive Prostate Cancer using Apalutamide	Eligibility updated			
UGMCSPDD	Treatment of Metastatic Castration Sensitive Prostate Cancer using Darolutamide and Docetaxel	Eligibility updated			
GUMCSPENZ	Treatment for Metastatic Castration Sensitive Prostate Cancer using Enzalutamide	Eligibility updated			
UGUNMPDAR	Treatment of Non- Metastatic Castration Resistant Prostate Cancer Using Darolutamide	Eligibility updated			
UGUNMPENZ	Therapy for Non-Metastatic Castration Resistant Prostate Cancer Using Enzalutamide	Eligibility updated			
UGUPABI	Palliative Therapy for Metastatic Castration Resistant Prostate Cancer Using Abiraterone and Prednisone	Eligibility updated			
UGUPAPA	Treatment of Non- Metastatic Castration Resistant Prostate Cancer Using Apalutamide	Eligibility updated			
UGUPAVOABI	Treatment for Metastatic Castration-Resistant Prostate Cancer using Olaparib with Abiraterone and Prednisone				
UGUPENZ	Palliative Therapy for Metastatic Castration Resistant Prostate Cancer Using Enzalutamide Eligibility updated				
UGUPOLAP	Treatment of Metastatic Castration-Resistant Prostate Cancer using Olaparib	Exclusions added			
HN Head and	Neck				
HNOTLEN	Therapy for Locally Recurrent or Metastatic, RAI- refractory Differentiated Thyroid Cancer Using Lenvatinib	Emetogenic risk category updated			
LU Lung					
LUAJNIVPP	Neoadjuvant Treatment of Non-Squamous Non-Small Cell Lung Cancer with Nivolumab, Pemetrexed and Platinum	Tests and dose modifications updated, duplicate hyperlinks removed	Tests updated		
LUAJNP	Adjuvant Cisplatin and Vinorelbine Following Resection of Non-Small Cell Lung Cancer	Eligibility, treatment dose modifications and precautions updated, exclusions removed	Treatment and tests updated		

	Protocols, PPPOs and Patient Hand		-	
Protocol Code	Protocol Title	Protocol	PPPO	Handout
LUAJPP	Adjuvant Cisplatin and Pemetrexed Following Resection of Non-Small Cell Lung Cancer	Tests and dose modifications updated	Tests updated	
LUAVPEM	Second-Line Chemotherapy of Advanced Non- Small Cell Lung Cancer With Pemetrexed	Tests and dose modifications updated, minor formatting	Tests updated	
LUAVPMTN	Maintenance Therapy of Advanced Non-Small Cell Lung Cancer With Pemetrexed	Tests and dose modifications updated, minor formatting	Tests updated	
LUAVPP	First-Line Treatment of Advanced Non-Small Cell Lung Cancer with Platinum and Pemetrexed	Tests and dose modifications updated, minor formatting	Tests updated	
LUAVPPIPNI	First-Line Treatment of Advanced Non-Squamous Non-Small Cell Lung Cancer with Platinum, Pemetrexed, Ipilimumab and Nivolumab	Tests and dose modifications updated	Tests updated (Cycle 1-2 PPPO)	
LUAVPPPMB	First-Line Treatment of Advanced Non-Squamous Non-Small Cell Lung Cancer with Platinum, Pemetrexed and Pembrolizumab	Tests and dose modifications updated, duplicate hyperlinks removed	Tests updated	
LUMMPP	Treatment of Malignant Mesothelioma with Platinum and Pemetrexed	Tests and dose modifications updated, minor formatting	Tests updated	
LUNETEV	Treatment of Advanced Neuroendocrine Tumours of Lung Origin (Non-Functional) Using Everolimus	Eligibility, notes, exclusion, treatment, dose modifications and precautions updated	Tests updated	
LY Lymphoma	1			
LYBENDO	Treatment of Rituximab-refractory Follicular Lymphoma with Bendamustine in Combination with Obinutuzumab	Treatment sequence changed, Title, tests, premedications, supportive medications, treatment, observation, vitals, and precautions updated, appendix clarified	Premedications, observation, vital sign requirements and tests updated, treatment sequence changed	
LYCHOPO	Treatment of Rituximab-refractory Follicular Lymphoma with Doxorubicin, Cyclophosphamide, Vincristine, Prednisone, and Obinutuzumab	Premedications, observation, vitals, and precautions updated, supportive medications and appendix clarified	Premedications, observation and vital sign requirements updated	

REVISED Protocols, PPPOs and Patient Handouts (revisions in respective columns)				
Protocol Code	Protocol Title	Protocol	PPPO	Handout
LYCVPO	Treatment of Rituximab-refractory Follicular Lymphoma with Cyclophosphamide, Vincristine, Prednisone and Obinutuzumab	Premedications, observation, vitals and precautions updated, supportive medications and appendix clarified	Premedications, observation, vital sign requirements, and tests updated	
ULYEPCOR	Treatment of Lymphoma using Epcoritamab	Eligibility, tests, and precautions updated	Tests updated	
LYEPOCHR	Treatment of Lymphoma with Dose Adjusted Etoposide, Doxorubicin, Vincristine, Cyclophosphamide, Prednisone and Rituximab with Intrathecal Methotrexate	Tests clarified		
LYGDPO	Treatment of Rituximab-refractory Follicular Lymphoma with Gemcitabine, Dexamethasone, Platinum and Obinutuzumab	Premedications, observation, vitals and precautions updated, supportive medications and appendix clarified	Premedications, vital sign requirements, and tests updated	
LYOBCHLOR	Treatment of Previously Untreated Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma with Obinutuzumab and Chlorambucil	Tests, premedications, observation, vitals, and precautions updated. Appendix clarified	Treatment clarified, premedications, observation, vitals, and tests updated	
LYVENOB	Treatment of Previously Untreated Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma using Venetoclax and Obinutuzumab	Premedications and administration clarified, tests, vitals, observation, precautions, and appendix updated	Premedications and rate clarified, observation, vital sign requirements, and tests updated	
SC Supportive Care				
SCCRS	Cytokine Release Syndrome Management	Grade 1 and 2 sections updated	Grade 1 and 2 sections updated	

Resources and Contact Information				
Resource	Phone	Email / Toll Free / Fax		
Systemic Therapy Update: www.bccancer.bc.ca/health-professionals/clinical-resources/systemic-therapy/systemic-therapy-update				
Systemic Therapy Update Editor	604-877-6000 x 672649	<u>bulletin@bccancer.bc.ca</u>		
Oncology Drug Information Cancer Drug Manual Editor Pharmacy Oncology Certification	604-877-6275 250-519-5500 x 693742 250-712-3900 x 686820	druginfo@bccancer.bc.ca nbadry@bccancer.bc.ca rxchemocert@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		
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 Network	604-877-6000 x 672247 604-877-6000 x 672623 604-877-6000 x 672247	mlin@bccancer.bc.ca BCCancerPPNAdmin@phsa.ca ProvincialSystemicOffice@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		

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