

Systemic Therapy Update

Volume 27 Issue 10 October 2024

For Health Professionals Who Care for People with Cancer

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GU UGUVHLBEL | LY ULYEPCOR

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HN HNLAALTPRT, HNLAPRT, HNNLAPRT, HNLACETRT |
GI UGIYTT | GU GUBDDMVAC | LU LUAVALE,
LUAVBRI, LUAVCER, LUAVCRIZ, LUAVCRIZF,
LUAVCRIZR | LY LYBENDR, LYCHLRR, LYCHOPR,
LYCHOPRMTX, LYCLLBENDR, LYCLLCHLR, LYCLLCVPR,
LYCLLFBR, LYCLLFLUDR, LYCVPR, LYDHAPR, LYFCR,
LYFLUDR, LYGDPR, LYIDELAR, LYPOLABR, LYRICE,
LYRITUX, LYRITZ, LYRMTN, ULYWMZANU | SA
SANADENO

Resources and Contact Information

Editor's Choice

New Programs

Effective 01 October 2024, 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

Belzutifan for von Hippel-Lindau (VHL) Disease-Associated Renal Cell Carcinoma, Hemangioblastomas and Pancreatic Neuroendocrine Tumours (UGUVHLBEL) – The BC Cancer Genitourinary Tumour Group is introducing belzutifan for patients with VHL-associated nonmetastatic renal cell carcinoma, hemangioblastomas, and nonmetastatic pancreatic neuroendocrine tumours, who do not require immediate surgery.

VHL is a rare, inherited disorder associated with formation of tumours in many different parts of the body. The phase II LITESPARK-004 study demonstrated that belzutifan therapy was associated with clinically meaningful objective response rate (>30%) in patients with renal cell carcinomas and non-renal cell

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carcinoma neoplasms associated with VHL.^{1,2} Anemia and fatigue are the most common side effects associated with belzutifan.

- 1. Jonasch E, Donskov F, Iliopoulos O, et al. Belzutifan for renal cell carcinoma in von Hippel-Lindau disease. N Engl J Med 2021;385:2036-46.
- 2. Belzutifan (Welireg) CADTH [Canada's Drug Agency (CDA-AMC)] Reimbursement Recommendation. Canadian Journal of Health Technologies Sep 2023; 3(9): 1-24.

Lymphoma

Epcoritamab for Treatment of Lymphoma (ULYEPCOR) – The BC Cancer Lymphoma Tumour Group is introducing epcoritamab, a bispecific T-cell antibody, for the treatment of relapsed and refractory lymphoma.

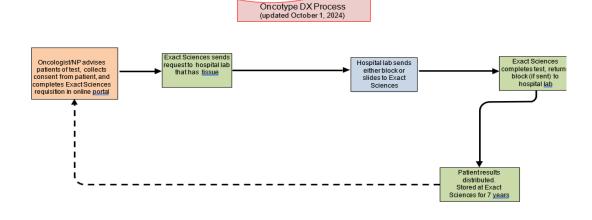
Evidence from an ongoing phase I/II indicates that treatment with epcoritamab may result in clinically meaningful improvements in overall survival, progression-free survival, complete response rate and duration of response. Epcoritamab is associated with cytokine release syndrome (CRS), neutropenia, anemia, and immune effector cell-associated neurotoxicity syndrome (ICANS).

- 1. Thieblemont C, Phillips T, Ghesquieres H, et al. Epcoritamab, a Novel, Subcutaneous CD3xCD20 Bispecific T-Cell-Engaging Antibody, in Relapsed or Refractory Large B-Cell Lymphoma: Dose Expansion in a Phase I/II Trial. J Clin Oncol. 2023 Apr 20;41(12):2238-2247.
- 2. CADTH [Canada's Drug Agency (CDA-AMC)] Reimbursement Review. Provisional Funding Algorithm. Large B cell lymphoma. Aug 2024.

Revised Programs

Breast

Effective 01 October 2024, requisition for the **Oncotype DX® Breast Cancer Assay** will no longer require the approval of the BC Cancer Compassionate Access Program (CAP). The process has been revised as below. More detailed information can be found on the BC Cancer website at: http://www.bccancer.bc.ca/lab-services-site



- Clinicians submit a signed patient consent form via fax or DocuSign to the Exact Sciences.
- For patients who does not meet eligibility, clinicians may submit CAP as outlined in the <u>BCCA Compassionate Access Program (CAP)</u> <u>Policy (III-45)</u>.

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Biosimilar Denosumab Available

Effective 01 October 2024, the BC Cancer Provincial Systemic Therapy Program is implementing the use of biosimilar denosumab in BC Cancer treatment protocol SANADENO.

The following highlights updates to BC Cancer documents:

• A Pharmacy Selection Box has been added to the SANADENO PPPO:

Pharmacy to select denosumab brand as per Provincial Systemic Therapy Policy III-190

| Drug | Brand (Pharmacist to complete. Please print.) | Pharmacist Initial and Date |
|-----------|---|-----------------------------|
| denosumab | | |

- Denosumab Monograph, Patient Handout and Chemotherapy Preparation and Stability Chart Revisions are specified in the Cancer Drug Manual section below.
- Oncology Biosimilars Utilization Policy [III-190] Updates are noted in the Provincial Systemic Therapy Program announcement below.

Compassionate Access Program

Website Update

BC Cancer Provincial Pharmacy is in the final phase of updating the Compassionate Access Program (CAP) website, with a planned launch date of 15 October 2024. Current CAP users will receive email notification of their account creation on 11 October 2024. The new CAP system will be located at https://bccancerpharmacy.ca.

The updates will provide health care providers with an enhanced functional experience and a more intuitive interface. By replacing an aging 18-year-old system, the goal is to improve the management of systemic drug therapy requests, further supporting optimal patient care at BC Cancer. Other benefits of the new CAP system will include:

- Users being able to access the CAP website anywhere in Canada with Microsoft Authenticator
- Designating a delegate (if needed) to submit CAP requests, and
- Attaching any relevant reference articles and studies directly to the CAP submission.

Other major changes include:

- All CAP users must now use their health authority email to sign on to the new CAP system; manual submission forms via fax will no longer be accepted. Users needing to update their email address can contact the CAP office at cap bcca@bccancer.bc.ca
- As with the recently updated OSCAR Online Drug Reimbursement program, the new CAP system will be based on the Personal Health Number (PHN) and will no longer use BC Cancer patient registration numbers.

Provincial Systemic Therapy

III-40 Policy and Procedure – Systemic Therapy Treatments

<u>Policy</u> and <u>Procedure</u> III-40 have been updated to better align with the evolving needs at BC Cancer. The revised policy now includes new guidelines for the delivery of unfunded drugs and has incorporated a section on Free Sample medications, previously covered under the now-retired III-70 - Free Samples of Medications Protocol. Additionally, two new appendices have been added to policy III-40:

Appendix A: Offers an overview of the drug review process, including unfunded drugs.
 Appendix B: Outlines the principles for supporting the delivery of unfunded cancer drug treatments at BC Cancer.

III-45 Policy and Procedure – Compassionate Access Program

<u>Policy</u> and <u>Procedure</u> III-45 have been updated to include language around unfunded drug delivery in relation to the Compassionate Access Program.

III-190 Policy and Procedure – Oncology Biosimilars Utilization

The BC Cancer Provincial Systemic Therapy Program has updated Policy III-190 – Oncology Biosimilars Utilization to include biosimilar denosumab. All Systemic Therapy policies can be found on the Shared Health Organizations Portal (SHOP) BC Cancer page.

Continuing Education

Family Practice Oncology Network Continuing Medical Education

The Family Practice Oncology Network (FPON) is pleased to announce a webinar session on 'Fertility Issues in Cancer Management' on Thursday, 17 October 2024, from 8 am to 9 am, as part of the Complimentary Accredited Webinar Series. The session will cover:

- Potential impacts of cancer treatments on fertility
- Options for fertility preservation
- Post cancer treatment fertility management approach

For more information and links to registration, visit:

https://ubccpd.ca/learn/learning-activities/course?eventtemplate=808-fpon-webinar-fertility-issues-incancer-management

Cancer Drug Manual[©]

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

New Documents

Note that the following drug is not a BC Cancer Benefit Drug and requires application to the Health Canada Special Access Program (SAP). The corresponding Interim Monograph and Patient Handout are made available for reference only.

The **Tarlatamab Interim Monograph** and **Patient Handout** have been developed. Expert review was provided by Dr. Barb Melosky (medical oncologist, BC Cancer Lung Tumour Group) and Megan Darbyshire (tumour group pharmacist, BC Cancer Provincial Pharmacy). Tarlatamab is a bispecific T-cell engager that simultaneously binds to delta-like ligand 3 (DLL3) on tumour cells and CD3 receptors on T-cells. Tarlatamab is used in the treatment of small cell lung cancer. Dosing follows a step-up dosing regimen for the first cycle, with doses given on days 1, 8, and 15. The usual dose for cycle 2 onwards is 10 mg IV given on days 1 and 15 in a 4-weekly cycle.

Highlights from these documents include:

- cytokine release syndrome (CRS) may occur with the first few doses; to mitigate the risk of CRS, tarlatamab is initiated in a step-up dosing regimen
- immune effector cell-associated neurotoxicity syndrome (ICANS) has been reported; most events occur during cycles 1 and 2
- Closed System Transfer Devices (CSTDs) cannot be used for preparation due to low volume extraction from the vial; Chemo-Vent® may be used to vent the vial during preparation

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

Revised Documents

Belzutifan Monograph and Patient Handout

Header and Footer: updated to remove interim designation

Dosage Guidelines: added new protocol UGUVHLBEL and bolded/italicized BC Cancer standard dosing

Patient Handout: updated Header and Footer to remove interim designation

Crisantaspase recombinant Chemotherapy Preparation and Stability Chart

Nomenclature: updated drug name to include "recombinant" in name

Denosumab Monograph, Patient Handout and Chemotherapy Preparation and Stability Chart

Common Trade Names: added biosimilar (WYOST)

Cautions: updated non-interchangeability statement; added calcium/vitamin D recommendation

Pregnancy: deleted FDA pregnancy category (ended in 2015); updated contraception recommendations

Supply and Storage: added biosimilar

Solution Preparation and Compatibility: updated to add biosimilar

Patient Handout: updated Name Banner to include biosimilar brand name; added recommendation duration for contraception to Pregnancy bullet; updated template wording throughout

Chemotherapy Preparation and Stability Chart: added WYOST biosimilar as new brand; added non-interchangeability statement and instructions for needle gauge to Special Precautions column for XGEVA

Epcoritamab Monograph and Patient Handout

Header and Footer: updated to remove interim designation

Parenteral Administration table: added new protocol ULYEPCOR and bolded/italicized BC Cancer

standard administration

Dosage Guidelines: added new protocol ULYEPCOR and bolded/italicized BC Cancer standard dosing Patient Handout: updated Header and Footer to remove interim designation; revised Side Effects table (created new standalone table for CRS and ICANS)

Trifluridine-Tipiracil Monograph

Dosage Guidelines: updated hepatic dosing

CDM Editorial Board Changes

The Cancer Drug Manual[©] Editorial Review Board would like to bid farewell to **Alysha Bharmal** (clinical pharmacist, BC Cancer – Surrey) as she returns to her clinical role in Surrey. Thank you, Alysha, for your many years of contributions to the Cancer Drug Manual[©], as both a CDM writer and as a CDM Editorial Board member. We wish you all the best in your future endeavours.

Benefit Drug List

New Programs

Effective 01 October 2024, the following new treatment programs have been added to the BC Cancer Benefit Drug List:

| Protocol Title | Protocol Code | Benefit Status |
|--|---------------|----------------|
| Belzutifan Therapy for von Hippel-Lindau Disease-Associated Renal Cell Carcinoma, Hemangioblastomas and Pancreatic Neuroendocrine Tumours | UGUVHLBEL | Restricted |
| Treatment of Lymphoma using Epcoritamab | ULYEPCOR | Restricted |

Revised Programs

Effective 01 October 2024, the following treatment programs have been revised on the BC Cancer Benefit Drug List:

| Protocol Title | Protocol Code | Benefit Status |
|--|----------------|---------------------------------------|
| Yttrium-90 for Transarterial Radioembolisation (TARE) for Hepatocellular Cancer or Neuroendocrine Tumours with Hepatic Disease | <u>U</u> GIYTT | Restricted (previously Class I) |

New and 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, 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 Pro | NEW Protocols, PPPOs and Patient Handouts (new documents checked ☑) | | | |
|-----------|--|----------|----------|---------|
| Code | Protocol Title | Protocol | PPPO | Handout |
| UGUVHLBEL | Belzutifan Therapy for von Hippel-Lindau Disease-Associated Renal Cell Carcinoma, Hemangioblastomas and Pancreatic Neuroendocrine Tumours | | V | |
| ULYEPCOR | Treatment of Lymphoma using Epcoritamab | | | |

| REVISED P | rotocols, PPPOs and Patient Han | douts (revisions | in respective co | lumns) |
|-----------------|--|---|---|---------|
| Code | Protocol Title | Protocol | PPPO | Handout |
| HN Head and F | HN Head and Heck | | | |
| HNLAALTPRT | Locally Advanced (Alternate) Head and Neck Cancer using CISplatin during Radiation Therapy | Title, tests, premedications, treatment, dose modifications and precautions updated | Premedications, treatment and tests updated | |

| REVISED P | REVISED Protocols, PPPOs and Patient Handouts (revisions in respective columns) | | | |
|-------------------|--|--|--|---------|
| Code | Protocol Title | Protocol | PPPO | Handout |
| HNLACETRT | Combined Cetuximab and Radiation Treatment for Locally Advanced Squamous Cell Carcinoma of the Head and Neck | Tests, premedications, and precautions updated | Pre-chemo metrics, treatment, return appointment and tests updated, vital signs and observation section created, magnesium supplementation moved, formatting | |
| HNLAPRT | Combined Chemotherapy CISplatin and Radiation Treatment for Locally Advanced Squamous Cell Carcinoma of the Head and Neck | Contact physician, staging and supportive care deleted, exclusions, premedications, tests, dose modifications, precautions and radiation therapy updated | Premedications, treatment and tests updated | |
| HNNLAPRT | Treatment of Locally Advanced Nasopharyngeal Cancer with Concurrent CISplatin and Radiation | Pre-treatment metrics, premedications, treatment and tests updated | Pre-treatment metrics and treatment clarified, premedications and tests updated | |
| GI Gastrointest | inal | | | |
| UGIYTT | Yttrium-90 for Transarterial Radioembolisation (TARE) for Hepatocellular Cancer or Neuroendocrine Tumours with Hepatic Disease | Protocol code changed, CAP requirement added, and eligibility updated | | |
| GU Genitourina | nry | | | |
| GUBDDMVAC | Neoadjuvant Treatment of Urothelial Cancer using Dose-Dense Methotrexate, vinBLAStine, DOXOrubicin and CISplatin | Dose modifications for renal dysfunction reformatted | | |
| LU Lung | | | | |
| LUAVALE | Treatment of ALK-Positive Advanced Non-Small Cell Lung Cancer (NSCLC) with Alectinib | Tests updated | Tests updated | |
| LUAVBRI | First-Line Treatment of ALK-Positive Advanced Non-Small Cell Lung Cancer (NSCLC) with Brigatinib | Tests updated | Tests updated | |
| LUAVCER | Treatment of ALK-Positive Advanced Non-Small Cell Lung Cancer (NSCLC) with Ceritinib | Tests updated | Tests updated | |
| LUAVCRIZ | Second-Line Treatment of ALK-Positive Advanced Non-Small Cell Lung Cancer (NSCLC) with Crizotinib | Tests updated | Tests updated | |

| REVISED Protocols, PPPOs and Patient Handouts (revisions in respective columns) | | | lumns) | |
|---|---|--|---------------|---------|
| Code | Protocol Title | Protocol | PPPO | Handout |
| LUAVCRIZF | First-Line Treatment of ALK-Positive Advanced Non-Small Cell Lung Cancer (NSCLC) with Crizotinib | Tests updated | Tests updated | |
| LUAVCRIZR | First-Line Treatment of ROS1-Positive Advanced Non-Small Cell Lung Cancer (NSCLC) with Crizotinib | Tests updated | Tests updated | |
| LY Lymphoma | | | | |
| LYBENDR | Treatment of Non-Hodgkin Lymphoma with Bendamustine and riTUXimab | Tests, supportive medications, treatment and precautions updated | Tests updated | |
| LYCHLRR | Treatment of Indolent B-cell Lymphoma with Chlorambucil and riTUXimab | Tests, supportive medications, treatment and precautions updated | Tests updated | |
| LYCHOPR | Treatment of Lymphoma with DOXOrubicin, Cyclophosphamide, vinCRIStine, predniSONE and riTUXimab (CHOP-R) | Tests, supportive medications, treatment, dose modifications and precautions updated | Tests updated | |
| LYCHOPRMTX | Central Nervous System Prophylaxis with High Dose Methotrexate, CHOP and riTUXimab in Diffuse Large B-Cell Lymphoma | Tests, supportive medications, treatment and precautions updated | Tests updated | |
| LYCLLBENDR | Treatment of Relapsed/Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma with Bendamustine and riTUXimab | Tests, supportive medications, treatment and precautions updated | Tests updated | |
| LYCLLCHLR | Treatment of Chronic Lymphocytic Leukemia with Chlorambucil and riTUXimab | Tests, supportive medications, treatment and precautions updated | Tests updated | |
| LYCLLCVPR | Treatment of relapsed Chronic Lymphocytic Leukemia using Cyclophosphamide, vinCRIStine, predniSONE and riTUXimab (CVP-R) | Tests, supportive medications, treatment and precautions updated | Tests updated | |
| LYCLLFBR | Treatment of Previously Untreated Chronic Lymphocytic Leukemia (CLL) with Bendamustine and riTUXimab | Tests, supportive medications, treatment and precautions updated | Tests updated | |

| REVISED P | REVISED Protocols, PPPOs and Patient Handouts (revisions in respective columns) | | | |
|------------|--|---|---------------|---------|
| Code | Protocol Title | Protocol | PPPO | Handout |
| LYCLLFLUDR | Treatment of Chronic Lymphocytic Leukemia or Prolymphocytic Leukemia with Fludarabine and riTUXimab | Tests, supportive medications, treatment and precautions updated | Tests updated | |
| LYCVPR | Treatment of Advanced Indolent Lymphoma using Cyclophosphamide, vinCRIStine, predniSONE and riTUXimab (CVP-R) | Tests, supportive medications, treatment and precautions updated | Tests updated | |
| LYDHAPR | Treatment of Lymphoma with Dexamethasone, Cytarabine, Platinum and riTUXimab | Tests, supportive medications, treatment and precautions updated | Tests updated | |
| LYFCR | Treatment of Chronic Lymphocytic Leukemia (CLL) or Prolymphocytic Leukemia with Fludarabine, Cyclophosphamide and riTUXimab | Tests, supportive medications, treatment and precautions updated | Tests updated | |
| LYFLUDR | Treatment of Relapsed Indolent Lymphoma with Fludarabine and riTUXimab | Tests, supportive medications, treatment and precautions updated | Tests updated | |
| LYGDPR | Treatment of Lymphoma with Gemcitabine, Dexamethasone and Platinum with riTUXimab | Tests, supportive medications, treatment and precautions updated | Tests updated | |
| LYIDELAR | Treatment of Relapsed/Refractory Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL) using Idelalisib and riTUXimab | Tests and treatment updated, supportive medications clarified | Tests updated | |
| LYPOLABR | Treatment of Relapsed or Refractory Diffuse Large B-Cell Lymphoma and Not Eligible for Transplant using Polatuzumab Vedotin, Bendamustine and riTUXimab | Tests, supportive medications, treatment and precautions updated | Tests updated | |
| LYRICE | Treatment of Relapsed or Refractory Advanced Stage Aggressive B-Cell Non-Hodgkin's Lymphoma with Ifosfamide, CARBOplatin, Etoposide and riTUXimab | Tests, supportive medications, treatment and precautions updated | Tests updated | |
| LYRITUX | Treatment of Lymphoma with Single Agent riTUXimab | Tests, supportive medications, treatment and precautions updated | Tests updated | |

| REVISED P | REVISED Protocols, PPPOs and Patient Handouts (revisions in respective columns) | | | |
|--------------|---|---|---|---------|
| Code | Protocol Title | Protocol | PPPO | Handout |
| LYRITZ | Palliative Therapy For Lymphoma Using Radioimmunotherapy: riTUXimab-Priming for 90Y-Ibritumomab Tiuxetan (ZEVALIN®) | Tests, supportive medications and precautions updated | Tests updated | |
| LYRMTN | Maintenance riTUXimab for Indolent Lymphoma | Tests, supportive medications and precautions updated | Tests updated | |
| ULYWMZANU | Treatment of Waldenström Macroglobulinemia or Lymphoplasmacytic Lymphoma (LPL) using Zanubrutinib | Tests updated, minor formatting | Tests updated | |
| SA Sarcoma | | | | |
| SANADENO | Denosumab for Neoadjuvant Use in Patients with Non-Metastatic Operable Giant Cell Tumour of the Bone | XGEVA brand name removed | Removed XGEVA brand name reference, inserted brand selection table | |

| Resource | Phone | Email / Toll Free / Fax |
|---|---|--|
| Systemic Therapy Update: www.bccance | er.bc.ca/health-professionals/cli | nical-resources/systemic-therapy/systemic-therapy-upda |
| Systemic Therapy Update Editor | 604-877-6000 x 672649 | bulletin@bccancer.bc.ca |
| 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 Program | 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 | 604-851-4710 250-712-3900 250-645-7300 604-930-2098 | toll free 877-547-3777 toll free 888-563-7773 toll free 855-775-7300 toll free 800-523-2885 |
| BC Cancer — Vancouver BC Cancer — Victoria | 604-877-6000 250-519-5500 | toll free 800-663-3333 toll free 800-670-3322 |

Editorial Review Board

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