Provincial Health Services Authority

Systemic Therapy Update

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For Health Professionals Who Care for Cancer Patients

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Editor's Choice

Hazardous Drug Exposure Control Program

The BC-wide **Hazardous Drug Exposure Control Program (ECP)** came into effect at BC Cancer in February 2022. The purpose of the Hazardous Drug ECP is to protect health care employees from the potential health hazards associated with hazardous drugs by minimizing or eliminating employees' potential occupational exposure to hazardous drugs. The ECP outlines the roles and responsibilities of employees to ensure occupational exposure remains as low as reasonably achievable and to attain regulatory compliance.

All health authorities in BC will be following the new Hazardous Drug ECP, creating a singular provincial approach to the management, classification and terminology of hazardous drugs. The Hazardous Drug ECP takes into account standards of the National Institute for Occupational Safety and Health (NIOSH), the National Association of Pharmacy Regulatory Authorities (NAPRA), Occupational Health and Safety (OHS) and Accreditation Canada. Each health authority will be implementing changes to align with the new Hazardous Drug ECP independently. Community Oncology Network (CON) hospitals will be working with their respective health authorities to implement any required changes.

As a part of the Hazardous Drug ECP implementation, the new **BC Provincial Hazardous Drug List** came into effect. This new hazardous drug list divides drugs into group 1 or group 2. **Hazardous Drug Group 1** contains drugs that have an accompanying Manufacturer Special Handling Information (MSHI) or are known or probable carcinogens. Many of the Group 1 hazardous drugs are cytotoxic and the majority are hazardous to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, and women who are breast feeding. Not all of the Group 1 hazardous drugs are antineoplastic drugs. **Hazardous Drug Group 2** contains hazardous drugs that do not have an accompanying MSHI and are not known or probable carcinogens. Both Group 1 and Group 2 drugs

represent an occupational hazard to healthcare workers and should always be handled with the use of recommended equipment and personal protective equipment (PPE), regardless of dosage form.

A change that health professionals will notice is that many of the hormonal agents are now classified as hazardous drugs. This includes drugs such as tamoxifen, aromatase inhibitors (e.g., anastrozole, exemestane, letrozole), and androgen receptor blockers (e.g., bicalutamide, enzalutamide). Therefore, drugs such as these will be labelled with a hazardous drug auxiliary label when dispensed to patients for take-home use, and pharmacists will provide counseling to patients on basic handling precautions.

The **BC Cancer Hazardous Drug List** continues to be available, and is now comprised of the BC Provincial Hazardous Drug List, and the **BC Cancer Addendum** to the BC Provincial Hazardous Drug List. The BC Cancer Addendum includes additional hazardous drugs evaluated by BC Cancer that have not yet been assessed by the BC Provincial Hazardous Drug List, such as drugs available through Health Canada's Special Access Program.

To support the implementation of the Hazardous Drug ECP, there are a number of new LearningHub eLearning Courses available. BC Cancer leadership teams should be in contact with employees regarding educational requirements.

BC Cancer has updated a number of Pharmacy, Systemic Therapy and Nursing directives, policies, procedures and practice references to align with the new requirements set out in the Hazardous Drug ECP. All updated documents are on the Shared Health Organizations Portal (SHOP) BC Cancer page and include:

Pharmacy	
II-40	NIOSH Alert Summary of Worker/Employer Recommendations
II-50	Certification Assessment Process for Safe and Aseptic Preparation of Parenteral Hazardous Drugs and other Parenteral Drugs
IV-10	Disposal of Drugs used in Clinical Trials
IV-70	ChemoLock Use in Clinical Trials
VI-10	Hazardous Drug Spill Control in Pharmacy *(retired; content merged with Systemic Therapy Procedure V-30: Spill Management of Hazardous Drugs)*
VI-60	Biological Safety Cabinets – Selection and Maintenance
VI-70	Guidelines for Preparation of Parenteral Hazardous Drugs for Latex Allergy Patients
VI-80	Hazardous Drug List
VI-100	Transportation of Hazardous Drugs
Systemic Therapy	
V-10	Hazardous Drug Safe Handling Policy
V-20	Employee Health: Management of Risks Related to Hazardous Drugs Practice Guidelines
V-30	Hazardous Drug Spill Management Procedure *(now serves as the hazardous drug spill management resource; replaces Provincial Pharmacy Directive VI-10: Hazardous Drug Spill Control in Pharmacy)*
Nursing	
C-252	Administration of Chemotherapeutic Agents
M-100	Administration of Medications
P-50	Personal Protective Equipment (PPE) for Safe Handling of Hazardous Drugs Procedure

Provincial Systemic Therapy Program

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

Updated: Remote Ordering of Systemic Therapy during COVID-19 Pandemic

Policy III-200: Remote Ordering of Systemic Therapy during COVID-19 Pandemic has been updated to reflect practice changes at BC Cancer. The use of online, fillable, PDF-format BC Cancer Pre-Printed Orders (PPOs) will no longer be supported. Moving forward, the SRFax web-based platform will be used for remote ordering of systemic therapy treatments. Each BC Cancer regional centre will create their own procedures as per operational requirements.

Updated: Vinca Alkaloid Preparation and Administration

Policy V-40: Vinca Alkaloid Preparation and Administration has been updated effective 01 March 2022. The updated policy provides more information on the safety rationale and requirements for staff involved in prescribing, preparing and administering vinca alkaloid preparations. Notably, the policy has undergone a name change from the previous *Dispensing and Labelling of Vinca Alkaloid Preparations* to the new **Vinca Alkaloid Preparation and Administration**.

Updated: High Alert Medications

The **BC Cancer Provincial High Alert Medications Policy** has been updated effective 01 March 2022; sirolimus NAB and tebentafusp have been added to the High Alert Medications List, and interferon alpha has been removed.

Patient Education

Updated: Natural Health Products and Breast Cancer

The **Natural Health Products and Breast Cancer** patient handout has been updated. A notable change is the removal of the table outlining hormone-containing natural health products. The number of products with known or suspected phytoestrogenic properties has increased substantially in recent years, limiting the feasibility of keeping such a table up-to-date. Due to conflicting evidence, the statement about vitamin D and cancer prevention has also been removed from the handout.

The Natural Health Products and Breast Cancer handout is available in the Complimentary and Alternative Therapies section on the BC Cancer website; a link is also provided on the Cancer Drug Manual© page.

For more information about natural health products, the handout refers patients to search in the Memorial Sloan Kettering Cancer Center About Herbs database. Health professionals can seek more information on natural health products in the professional monographs of the Natural Medicines resource; patient handouts are also available within this resource.

Cancer Drug Manual©

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

New Documents

Note that the following drugs are not BC Cancer Benefit Drugs and require application to the BC Cancer Compassionate Access Program (CAP). The corresponding Interim Monographs and Patient Handout are made available for reference only.

The **Decitabine-Cedazuridine Interim Monograph** and **Patient Handout** have been developed with expert review provided by Dr. Tom Nevill (hematologist, Leukemia/BMT Program of BC) and Katie Lacaria (clinical pharmacist, Leukemia/BMT – VGH). Decitabine-cedazuridine is composed of a nucleoside metabolic inhibitor (decitabine), used for its antineoplastic effects, and a cytidine deaminase inhibitor (cedazuridine), used to enhance the bioavailability of decitabine. Decitadine-cedazuridine is used in the treatment of myelodysplastic syndromes. The usual dose is 35 mg-100 mg (1 tablet) given once daily on days 1 to 5 of each 28-day cycle.

Highlights from these documents include:

- myelosuppression is common; febrile neutropenia is reported in one-third of patients
- severe thrombocytopenia may lead to serious bleeding-related adverse events
- tablets should be taken on an empty stomach, at least 2 hours before or 2 hours after a meal (note: this is not the standard recommendation for empty stomach administration)

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

The **Sirolimus NAB Interim Monograph** has been developed. Sirolimus is a potent mTOR inhibitor. Sirolimus NAB is a human albumin-bound formulation of sirolimus, created to improve the low water solubility of the drug for intravenous and intravesical administration. Sirolimus NAB is used in the treatment of perivascular epithelioid cell tumour (PEComa). The usual dose is 100 mg/m^2 IV given on days 1 and 8 of a 21-day cycle.

Highlights from this document include:

- hypersensitivity reactions are reported with both albumin and oral sirolimus; increased monitoring is recommended, particularly for the first infusion
- the effectiveness of vaccines may be compromised during treatment; immunizations should be updated prior to treatment if possible
- administration with a 15 micron (or larger) filter is recommended to prevent the administration of proteinaceous strands which may develop during preparation

Sirolimus NAB has been added to the **Chemotherapy Preparation and Stability Chart** and has been evaluated for the **BC Cancer Hazardous Drug List.**

Cancer Drug Manual©

The **Tebentafusp Interim Monograph** has been developed. Tebentafusp is a fusion protein composed of a soluble T-cell receptor fused to an anti-CD3 monoclonal antibody. It exerts its effect by stimulating the immune system to attack the target tissue by activating T-cells in physical contact with the malignant tissue. Tebentafusp is used for the treatment of HLA-A*02:01 positive patients with uveal melanoma. For the first cycle, tebentafusp is given in an inpatient setting as an escalating dose on days 1, 8 and 15 of a 21-day cycle. For subsequent cycles, tebentafusp is given as a fixed dose on days 1, 8 and 15.

Highlights from this document include:

- severe cytokine release syndrome has been reported; most events occur after the first dose
- tumour flare or pain may occur due to inflammation secondary to immune activation
- skin toxicity is among the most frequent adverse events; with repeated dosing, the majority of symptoms reduce in severity and duration

Tebentafusp has been added to the **Chemotherapy Preparation and Stability Chart** and has been evaluated for the **BC Cancer Hazardous Drug List.**

Revised Documents

Octreotide slow release injection suspension
Chemotherapy Preparation and Stability Chart: added new brand (Teva)

Community Oncology Network (CON)

2021-2022 OSCAR Billing Deadline: 05 April 2022

The 2021-2022 fiscal year will end on Thursday 31 March 2022. To meet the deadline for external reporting to the Ministry of Health, all claims for drug reimbursement for the current fiscal year must be submitted by **Tuesday 05 April 2022** via **OSCAR** (**O**nline **S**ystem for **C**ancer Drugs **A**djudication and **R**eimbursement). Any claims submitted after this date will not be eligible for reimbursement. For more information, please e-mail oscar@bccancer.bc.ca.

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
UHNAVPMBF6	First-Line Treatment of Advanced Squamous Cell Carcinoma of the Head and Neck using 6-Weekly Pembrolizumab	☐	☐	☑
HNAVPMBM6	Maintenance Treatment of Advanced Squamous Cell Carcinoma of the Head and Neck using 6-Weekly Pembrolizumab	☐	☐	☑

REVISED Protocols, PPPOs and Patient Handouts *(revisions in respective columns)*

Protocol Code	Protocol Title	Protocol	PPPO	Handout
BR | Breast				
BRAJANAS	Neoadjuvant or Adjuvant Therapy for Breast Cancer using Anastrozole in Postmenopausal Women	*Eligibility and Treatment updated*	-----	-----
BRAJEXE	Neoadjuvant or Adjuvant Therapy for Breast Cancer using Exemestane in Postmenopausal Women	*Eligibility and Treatment updated*	-----	-----
BRAJLET	Neoadjuvant or Adjuvant Therapy for Breast Cancer using Letrozole in Postmenopausal Women	*Eligibility and Treatment updated*	-----	-----
BRAJTAM	Neoadjuvant or Adjuvant Therapy for Breast Cancer using Tamoxifen	*Eligibility and Treatment updated*	-----	-----
BRLACTWACG	Neoadjuvant Therapy for Triple-Negative Breast Cancer using Dose-Dense Therapy: Carboplatin and Weekly Paclitaxel followed by Doxorubicin and Cyclophosphamide	-----	*Optional filgrastim teach added for cycles 1-4*	-----
GI | Gastrointestinal				
GIAAVCT	First-Line Palliative Treatment of Metastatic Anal Squamous Cell Carcinoma using Carboplatin and Weekly Paclitaxel	*Treatment updated*	-----	-----
GIGAVCOX	Palliative Treatment of Metastatic or Locally Advanced Gastric, Gastroesophageal Junction or Esophageal Carcinoma using Capecitabine and Oxaliplatin	*Title and Eligibility updated*	-----	-----

REVISED Protocols, PPPOs and Patient Handouts *(revisions in respective columns)*

Protocol Code	Protocol Title	Protocol	PPPO	Handout
GIGAVCOXT	Palliative Treatment of Metastatic or Locally Advanced Gastric, Gastroesophageal Junction or Esophageal Adenocarcinoma using Capecitabine, Oxaliplatin and Trastuzumab	*Eligibility updated*	-----	-----
GIGAVFFOX	Palliative Treatment of Metastatic or Locally Advanced Gastric, Gastroesophageal Junction or Esophageal Carcinoma using Oxaliplatin, Fluorouracil and Leucovorin	*Title and Eligibility updated*	-----	-----
GIGAVFFOXT	Palliative Treatment of Metastatic or Locally Advanced Gastric, Gastroesophageal Junction or Esophageal Adenocarcinoma using Oxaliplatin, Fluorouracil, Leucovorin and Trastuzumab	*Eligibility updated*	-----	-----
GIPE	Palliative Therapy of Neuroendocrine Tumours using Cisplatin and Etoposide	*Precautions clarified*	-----	-----
GIRAJCOX	Adjuvant or Neoadjuvant Combination Chemotherapy for Stage III Rectal Cancer using Oxaliplatin and Capecitabine	*Eligibility updated*	-----	-----
GO | Gynecologic				
GOENDCAT	Treatment of Primary Advanced or Recurrent Endometrial Cancer using Carboplatin and Paclitaxel	*Contact Physician updated; Eligibility revised*	-----	-----
LK | Leukemia				
LKATOATRA	First-Line Induction and Consolidation Therapy of Acute Promyelocytic Leukemia using Arsenic Trioxide and Tretinoin (All-Trans Retinoic Acid)	*Disease monitoring revised*	-----	-----
LKATOP	First-Line Induction and Consolidation Therapy of Acute Promyelocytic Leukemia using Arsenic Trioxide, Tretinoin (All-Trans Retinoic Acid) and Daunorubicin	*Disease monitoring revised*	-----	-----
LY | Lymphoma				
LYABVD	Treatment of Hodgkin's Disease with Doxorubicin, Bleomycin, Vinblastine and Dacarbazine	*IV bag and in-line filter clarified*	*IV bag and in-line filter clarified*	-----
LYASPMEDEX	Treatment of Refractory or Relapsing Extranodal Natural Killer or T-Cell Lymphoma using Pegaspargase, Methotrexate and Dexamethasone	*Tests, vitals monitoring, hemoglobin transfusion threshold and pegaspargase dose revised*	*Tests, vitals monitoring and pegaspargase dose revised* **Inpatient PPO**	-----
LYCHOPRMTX	Central Nervous System Prophylaxis with High-Dose Methotrexate, CHOP and Rituximab in Diffuse Large B-Cell Lymphoma	*Optional LFTs added post MTX*	*Optional LFTs added post MTX* **Inpatient PPO**	-----

REVISED Protocols, PPPOs and Patient Handouts *(revisions in respective columns)*				
Protocol Code	**Protocol Title**	**Protocol**	**PPPO**	**Handout**
LYCODOXMR	Treatment of Burkitt's Lymphoma and Leukemia (ALL-L3) with Cyclophosphamide, Vincristine, Doxorubicin, Methotrexate, Leucovorin (CODOX-M) and Rituximab	*Optional LFTs added post MTX*	*Optional LFTs added post MTX*	-----
LYHDMRTEM	Treatment of Primary and Secondary CNS Lymphoma with High-Dose Methotrexate, Rituximab and Temozolomide	*Optional LFTs added post MTX*	*Optional LFTs added post MTX* **Inpatient PPO**	-----
LYHDMTXPRO	Central Nervous System Prophylaxis with High-Dose Methotrexate in Diffuse Large B-Cell Lymphoma	*Optional LFTs added post MTX; treatment day clarified*	*Optional LFTs added post MTX* **Inpatient PPO**	-----
LYOBCHLOR	Treatment of Previously Untreated Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma with Obinutuzumab and Chlorambucil	*Eligibility, day 1 vitals monitoring and frequency of hepatitis DNA test clarified*	*Day 1 vitals monitoring clarified*	-----
LYSMILE	Treatment of Natural Killer or T-Cell Lymphoma using Dexamethasone, Methotrexate, Ifosfamide, Pegaspargase and Etoposide	*Eligibility and Exclusions clarified; Tests, vitals monitoring, hemoglobin transfusion threshold and pegaspargase dose revised*	*Tests, vitals monitoring and pegaspargase dose revised* **Inpatient PPO**	-----
LYVENOB	Treatment of Previously Untreated Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma using Venetoclax and Obinutuzumab	*Day 1 vitals monitoring clarified*	*Day 1 lab timing revised; day 1 vitals monitoring clarified; allopurinol confirmation added to TLS prophylaxis section* **Cycle 1 & Cycle 2 Low/Med-Risk PPOs**	-----
MY | Myeloma				
UMYCARDEX	Therapy of Multiple Myeloma using Carfilzomib and Dexamethasone with or without Cyclophosphamide	-----	*Day 1 labs rearranged*	-----
UMYDARBD	Treatment of Relapsed and Refractory Multiple Myeloma with Daratumumab in Combination with Bortezomib and Dexamethasone with or without Cyclophosphamide	*Premedications clarified*	-----	-----
UMYDARLD	Treatment of Relapsed and Refractory Multiple Myeloma with Daratumumab in Combination with Lenalidomide and Dexamethasone	*Premedications clarified*	-----	-----

REVISED Protocols, PPPOs and Patient Handouts *(revisions in respective columns)*

Protocol Code	Protocol Title	Protocol	PPPO	Handout
SA | Sarcoma				
SAAJAP	Adjuvant Therapy for Osteosarcoma using Doxorubicin and Cisplatin	*Premedications revised*	*Premedications revised* **Inpatient PPO**	-----
SAAVAP	Therapy of Advanced Osteosarcoma using Doxorubicin and Cisplatin	*Premedications revised*	*Premedications revised* **Inpatient PPO**	-----

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	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.ca/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: bulletin@bccancer.bc.ca		

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