Systemic Therapy Update

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CARE + RESEARCH
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EDITOR'S CHOICE

NEW PROGRAMS

The Provincial Systemic Therapy Program has approved the following programs effective 01 May 2014:

Breast:

Trastuzumab Emtansine (KADCYLA®) for Metastatic Breast Cancer (UBRAVKAD) – The BCCA Breast Tumour Group has implemented trastuzumab emtansine for patients with HER2-positive metastatic breast cancer who have:

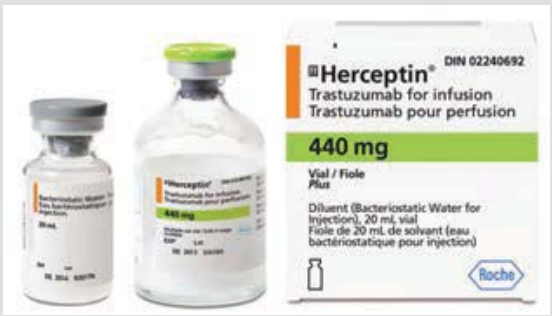
- had prior treatment with trastuzumab plus chemotherapy in the metastatic setting, or
- disease recurrence during adjuvant therapy with trastuzumab plus chemotherapy, or within 6 months of completing treatment

Of note, the BCCA Compassionate Access Program will only approve up to two lines of anti-HER2 therapies in the metastatic setting.

Approval of this program was based on the EMILIA trial, an open-label phase III trial that compared trastuzumab emtansine to lapatinib plus capecitabine in HER2-positive metastatic breast cancer patients who had previously been treated with trastuzumab and a taxane.[1] Median overall survival (mOS) and progression free survival (mPFS) were both in favour of trastuzumab emtansine (mOS 30.9 mo vs. 25.1 mo, HR 0.68, 95% CI 0.55-0.85) (mPFS 9.6 mo vs. 6.4 mo, HR 0.65, 95% CI 0.55-0.77). Compared to lapatinib plus capecitabine, trastuzumab emtansine was associated with a delay in deterioration of quality of life, fewer grade 3 or above diarrhea and hand-foot syndrome, but higher rates of overall thrombocytopenia and elevated aspartate aminotransferase. The incidence of grade 3 or higher left ventricular systolic dysfunction was similar between the treatment arms. For pharmacologic information about trastuzumab emtansine, please see the Cancer Drug Manual section below.

Medication Safety Alert: Please be mindful of the look-alike, sound-alike nature of trastuzumab emtansine (KADCYLA®) and trastuzumab (HERCEPTIN®), as drug selection and dispensing errors have been reported. Trastuzumab emtansine (KADCYLA®) is supplied as 100 mg and 160 mg vials while trastuzumab (HERCEPTIN®) is supplied as a 440 mg vial.

A. Canadian product packaging for trastuzumab emtansine (KADCYLA®)[2]



B. Canadian product packaging for trastuzumab (HERCEPTIN®)[2]

To reduce the risk of selection errors during the dispensing process, all BCCA medication-related databases as well as chemotherapy protocols and pre-printed orders containing trastuzumab and trastuzumab emtansine have been updated to include both the generic and brand names.

References:
1. Verma S, Miles D, Gianni L, et al. Trastuzumab emtansine for HER2-positive advanced breast cancer. NEJM 2012;367:1783-1791.
2. ISMP Canada Safety Bulletins. Look-alike/sound-alike ALERT: Trastuzumab emtansine (Kadcyla) and trastuzumab (Herceptin). Vol 13 Issue 10. November 4, 2013. http://ismp-canada.org/ISMPCSafetyBulletins.htm

Leukemia/BMT:

The BC Leukemia/BMT Tumour Group has implemented the following three programs in patients with acute promyelocytic leukemia (APL):

- **Arsenic Trioxide with Tretinoin (All-*Trans* Retinoic Acid, or ATRA) for First-Line Induction and Consolidation Therapy of Acute Promyelocytic Leukemia (ULKATOATRA)** – In patients with newly diagnosed APL of low to intermediate risk (defined as a WBC less than 10 x 10^9/L), ATRA plus arsenic trioxide was superior to ATRA plus standard chemotherapy in complete remission rates (100% vs. 95%), 2-year disease-free survival (97% vs. 90%), and 2-year overall survival (99% vs. 91%). [Lo-Coco et al. NEJM 2013;369:111-121] ATRA plus arsenic trioxide was associated with higher rates of grades 3 and 4 hepatotoxicity and QT-prolongation, but lower rates of myelosuppression and infections.

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- **Arsenic Trioxide Alone for First-Line Consolidation Therapy of Acute Promyelocytic Leukemia (ULKATOP)** – In patients with high-risk APL (defined as a WBC of greater than 10 x 10^9/L) who have received induction therapy with ATRA and chemotherapy, first-line consolidation therapy with arsenic trioxide was associated with superior 3-year event-free survival (80% vs. 63%), 3-year overall survival (86% vs. 81%), and disease-free survival (90% vs. 70%) when compared to standard consolidation therapy with ATRA and chemotherapy. [Powell et al. Blood 2010;116:3751-3757]

- **Arsenic Trioxide Alone for Induction and Consolidation Therapy of Relapsed Acute Promyelocytic Leukemia (ULKATOR)** – In patients with relapsed or refractory APL demonstrating t(15,17) translocation and PML/RAR-alpha gene expression, induction and consolidation therapy with arsenic trioxide was associated with a 66% 18-month overall survival rate, and a 56% 18-month relapse free survival rate. [Soignet et al. JCO 1001;19:3852-3860] Leukocytosis and QT-prolongation were experienced by 50% and 63% of patients, respectively.

Lymphoma:

Etoposide, Dexamethasone and Cyclosporine for the Treatment of Hemophagocytic Lymphohistiocytosis (HLHETCSPA) – The Leukemia/BMT Tumour Group has implemented this program based on data suggesting improved survival in patients with hemophagocytic lymphohistiocytosis.

Sarcoma:

Topotecan and Cyclophosphamide for Recurrent/Refractory Neuroblastoma, Ewing's Sarcoma, Osteogenic Sarcoma or Rhabdomyosarcoma (SAAVTC) – The BCCA Sarcoma Tumour Group has implemented this program based on several phase II trials that demonstrated good disease response in these patient populations. [Saylors et al. JCO 2001;19:3463-3469] [Hunold et al. Pediatr Blood Cancer 2006;47:795-800] The primary toxicity associated with this regimen was myelosuppression.

HIGHLIGHTS OF CHANGES IN PROTOCOLS, PPPOS AND PATIENT HANDOUTS

The Provincial Systemic Therapy Program has revised the following program effective 01 May 2014:

Lung:

Expanding Eligibility Criteria of Maintenance Pemetrexed Therapy in Advanced Non-Small Cell Lung Cancer (ULUAVPMTN) – Single-agent pemetrexed was previously approved as maintenance therapy only in patients with stable disease after treatment with a platinum-based doublet that did not contain pemetrexed. In the landmark PARAMOUNT study, maintenance pemetrexed was shown to improve the median overall survival (13.9 mo vs. 11.0 mo, HR 0.78, 95% CI 0.64-0.96) in NSCLC patients with stable disease after 4 cycles of pemetrexed and cisplatin. [Paz-Ares LG et al. JCO 2013;31:2895-2902] Based on these results, the ULUAVPMTN protocol has been revised to include patients who have not experienced disease progression after 4 to 6 cycles of first-line platinum-based doublet with or without pemetrexed.

Provincial Systemic Therapy Program

Updates to BCCA Policy on Physician Coverage for Medical Emergencies During Delivery of Selective Chemotherapy Drugs

The BCCA Systemic Therapy Policy (III-60) on Physician Coverage for Medical Emergencies During Delivery of Selected Chemotherapy Drugs has been updated to include bendamustine, brentuximab, cabazitaxel, pertuzumab and trastuzumab emtansine.

Communities Oncology Network

Use of BCCA Policies and Procedures

Please be reminded that the BCCA Provincial Systemic Therapy Program Policies and Procedures are intended to govern practice at the 6 regional cancer centres only, and are accessible on the BCCA website for information purposes. They have not been designed for use at any other health care institution. While the BCCA has a provincial mandate to develop high standards for cancer-related patient care, it does not have jurisdiction over the delivery of patient care outside the BCCA. The use of these policies by other health care institutions is the sole responsibility of those institutions. It is recommended that health authorities in the province of BC develop chemotherapy delivery processes for standardized patient care and patient safety within their own centres. Health authorities may wish to use the BCCA policies and procedures as templates when creating their own.

Drug Update

Biohazardous Drugs and Safe Handling Procedures

The BCCA Pharmacy Communities Oncology Network (CON) Educators have recently updated information on Biohazardous Drugs and the safe handling procedures for these agents in the Frequently Asked Questions section of the BCCA Pharmacy webpage.

Highlights of this document include:

- A biohazardous drug is defined as a drug that contains living organisms with the potential to cause infections in humans
  e.g.) Bacille Calmette-Guerin (BCG) vaccine, Reovirus Serotype 3 – Dearing Strain (REOLYSIN®)
- Microorganisms contained in biohazardous drugs are unlikely to cause infections in healthy individuals, but may cause nosocomial infections in immunocompromised individuals. To prevent such infections, special disinfecting procedures must be followed when handling biohazardous drugs. The following BCCA Systemic Therapy Policies and Procedures have been updated to include safe handling procedures for biohazardous drugs:
  - V-10 – Hazardous Drug Safe Handling Standards
  - V-20 – Employee Health: Management of Risks Related to Hazardous Drugs
  - V-30 – Hazardous Drug Spill Management

CANCER DRUG MANUAL

NEW MONOGRAPHS AND PATIENT HANDOUTS

Trastuzumab emtansine Interim Monograph has been expanded to a **Full Monograph**, and a **Patient Handout** has been created. Expert review was provided by Dr. Vanessa Bernstein, BCCA Breast Systemic Group Chair.

The monograph now includes:

- *Pharmacokinetics* table
- *Interactions* section
- Expanded information on *Special Precautions*, *Side Effects* and *Dosage Guidelines*
- Updated information in the *Supply and Storage* section

Highlights include:

- Trastuzumab emtansine (KADCYLA®) is NOT interchangeable with trastuzumab (HERCEPTIN®).
- The drug should NOT be diluted with dextrose-containing solutions.
- Hepatotoxicity, mainly in the form of asymptomatic increases in serum transaminases, has been observed. Hyperbilirubinemia and nodular regenerative hyperplasia have also been reported. Patients may require a dose reduction, treatment interruption, or permanent discontinuation of therapy.
- Interstitial lung disease, including pneumonitis, has been reported. Treatment should be permanently discontinued in these patients.

REVISED MONOGRAPHS AND PATIENT HANDOUTS

Highlights of key changes and/or updates to the Monographs and Patient Handouts are listed below:

Azacitidine:

- **Monograph:**
  - *Solution Preparation and Compatibility* section – added information on cold diluent reconstitution

Cytarabine:

- **Monograph:**
  - *Supply and Storage* section – updated available brands

Nilotinib:

- **Monograph and Handout:**
  - *Pharmacokinetic table* – added pH-dependent solubility
  - *Interactions table* – added interactions with drugs affecting gastric pH such as antacids, H2-receptor antagonists, and proton pump inhibitors

TRANSLATED PATIENT HANDOUTS

The following Patient Handouts have been translated into Chinese and Punjabi:

- Cyclophosphamide Injection
- Etoposide Injection
- Hydroxyurea

Benefit Drug List

New Programs

The following programs have been added to the Benefit Drug List effective 01 May 2014:

Protocol Title	Protocol Code	Benefit Status
Palliative Therapy for Metastatic Breast Cancer using Trastuzumab Emtansine (KADCYLA)	UBRAVKAD	Restricted
Treatment of Hemophagocytic Lymphohistiocytosis with Etoposide, Dexamethasone and cycloSPORINE	HLHETCSPA	Class II
First-Line Induction and Consolidation Therapy of Acute Promyelocytic Leukemia Using Arsenic Trioxide and Tretinoin (All-Trans Retinoic Acid)	ULKATOATRA	Restricted
First-Line Consolidation Therapy of Acute Promyelocytic Leukemia Using Arsenic Trioxide	ULKATOP	Restricted
Induction and Consolidation Therapy of Relapsed Acute Promyelocytic Leukemia Using Arsenic Trioxide	ULKATOR	Restricted
Summary for Treatment of Recurrent/refractory Neuroblastoma, Ewing's Sarcoma, Osteogenic Sarcoma or Rhabdomyosarcoma with Topotecan/Cyclophosphamide	SAAVTC	Class II

Revised Programs

The following program has been revised in the Benefit Drug List effective 01 May 2014:

Protocol Title	Protocol Code	Benefit Status
Treatment with Subcutaneous or Intravenous Alemtuzumab for Fludarabine-Refractory B-Chronic Lymphocytic Leukemia (B-CLL) or with Intravenous Alemtuzumab for Previously Untreated T-Prolymphocytic Leukemia (T-PLL)	LYALEM	Class II (Previously Restricted)

Systemic Therapy Update

Editorial Board Membership

The BCCA Systemic Therapy Update Editorial Board would like to bid farewell to Susan Walisser, Pharmacy Professional Practice Leader – VIC and Provincial Pharmacy, who has served on the Board for the past decade. The Board would like to thank Susan for her tremendous contributions and guidance to the editorial process over the years, and wishes her the best in her future endeavours. The Board would also like to welcome a new member, Rob Watt, Pharmacy Professional Practice Leader – CN.

List of New and Revised Protocols, Pre-Printed Orders and Patient Handouts

BC Cancer Agency 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. Protocol codes for treatments requiring "Compassionate Access Program" (previously Undesignated Indications Request) approval are prefixed with the letter "U".

NEW Protocols, PPPOs and Patient Handouts (affected documents are checked):

CODE	Protocol	PPPO	Patient Handout	Protocol Title
UBRAVKAD	☑	☑	☐	Palliative Therapy for Metastatic Breast Cancer using Trastuzumab Emtansine (KADCYLA)
HLHETCSPA	☑	☑	☐	Treatment of Hemophagocytic Lymphohistiocytosis with Etoposide, Dexamethasone and cycloSPORINE
HNAVP	☐	☐	☑	Palliative Chemotherapy for Advanced Head and Neck Squamous Cell Carcinoma with Weekly CISplatin
HNNAVP	☐	☐	☑	Palliative Chemotherapy for Advanced Head and Neck Nasopharyngeal Carcinoma with Weekly CISplatin
UHNNAVPC	☐	☐	☑	Treatment of Recurrent or Metastatic Nasopharyngeal Carcinoma with CARBOplatin and PACLitaxel
ULKATOATRA	☑	☐	☐	First-Line Induction and Consolidation Therapy of Acute Promyelocytic Leukemia Using Arsenic Trioxide and Tretinoin (All-Trans Retinoic Acid)
ULKATOP	☑	☐	☐	First-Line Consolidation Therapy of Acute Promyelocytic Leukemia Using Arsenic Trioxide
ULKATOR	☑	☐	☐	Induction and Consolidation Therapy of Relapsed Acute Promyelocytic Leukemia Using Arsenic Trioxide
ULUAVCRIZ	☐	☐	☑	Second-Line Treatment of ALK-Positive Advanced Non-Small Cell Lung Cancer (NSCLC) with Crizotinib
SAAVTC	☑	☑	☐	Treatment of Recurrent/Refractory Neuroblastoma, Ewing's Sarcoma, Osteogenic Sarcoma or Rhabdomyosarcoma with Topotecan/ Cyclophosphamide
SCDMAB	☑	☐	☐	Treatment of Prostate Cancer Bone Metastases using Denosumab (XGEVA®)

REVISED Protocols, PPPOs and Patient Handouts (affected documents are checked):

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
UBRAVERIB	☑	☐	☐	*Dose modifications for renal and hepatic impairment clarified*	Palliative Therapy for Metastatic Breast Cancer using Eribulin
BRAVEXE	☑	☐	☐	*Minor typo corrected*	Palliative Therapy for Advanced Breast Cancer Using Exemestane

REVISED PROTOCOLS, PPPOS AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED):					
CODE	**Protocol**	**PPPO**	**Patient Handout**	**Changes**	**Protocol Title**
BRAVT7	☑	☐	☐	*Reference added, TALLman lettering formatted*	Palliative Therapy for Metastatic Breast Cancer using Weekly PACLitaxel
UBRAVLCAP	☑	☐	☐	*Eligibility clarified*	Therapy for Metastatic Breast Cancer Using Capecitabine and Lapatinib
UBRAVTCAP	☑	☐	☐	*Eligibility clarified*	Palliative Therapy for Metastatic Breast Cancer using Trastuzumab and Capecitabine
CNAJTZRT	☑	☐	☐	*Dose Modifications clarified*	Concomitant (Dual Modality) and Adjuvant Temozolomide for Newly Diagnosed Malignant Gliomas with Radiation
CNOCTLAR	☑	☐	☐	*Eligibility clarified*	Treatment of Growth Hormone Secreting Pituitary Adenoma Using Octreotide
GIEFUPRT	☑	☐	☐	*Test clarified*	Combined Modality Therapy for Locally Advanced Esophageal Cancer using CISplatin, Infusional Fluorouracil and Radiation Therapy
GIPAJGEM	☑	☐	☐	*Eligibility clarified*	Adjuvant Chemotherapy for Pancreatic Adenocarcinoma Using Gemcitabine
GIRCRT	☑	☑	☐	*Eligibility updated*	Combined Modality Adjuvant Therapy for High Risk Rectal Carcinoma using Capecitabine and Radiation Therapy
GOOVDDCAT	☐	☑	☐	*Dosing scheduling clarified*	Treatment Of Advanced Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Carcinoma Using CARBOplatin and Weekly PACLitaxel
UGUAXIT	☑	☐	☐	*Minor typo corrected*	Therapy for Metastatic Renal Cell Carcinoma Using Axitinib
UGUPENZ	☑	☐	☐	*Treatment section clarified*	Palliative Therapy for Metastatic Castration Resistant Prostate Cancer Using Enzalutamide
UGUSORAF	☑	☑	☐	*Test clarified*	Palliative Therapy for Renal Cell Carcinoma Using Sorafenib
HNAVP	☑	☐	☐	*Dose modifications updated*	Palliative Chemotherapy for Advanced Head and Neck Squamous Cell Carcinoma with Weekly CISplatin
UHNLADCF	☐	☐	☑	*Frequency of hair loss clarified*	Treatment of Locally Advanced Squamous Cell Carcinoma of the Head and Neck with DOCEtaxel, CISplatin and Infusional Fluorouracil
HNNAVPE	☐	☐	☑	*Minor revisions of wording*	Treatment of Recurrent and/or Metastatic Nasopharyngeal Cancer with Platinum and Etoposide

REVISED PROTOCOLS, PPPOS AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED):					
CODE	**Protocol**	**PPPO**	**Patient Handout**	**Changes**	**Protocol Title**
UHNLACETRT	☑	☑	☐	*Magnesium supplementation added*	Combined Cetuximab and Radiation Treatment for Locally Advanced Squamous Cell Carcinoma of the Head and Neck
HNNLAPRT	☑	☐	☐	*Typo corrected in Exclusions*	Treatment of Locally Advanced Nasopharyngeal Cancer with Concurrent CISplatin and Radiation
LKCMLI	☐	☑	☐	*Tests clarified*	Therapy for Chronic Myeloid Leukemia and Ph+ Acute Lymphoblastic Leukemia Using Imatinib
ULKCMLD	☐	☑	☐	*Tests clarified*	Treatment of Chronic Myeloid Leukemia and Ph+ Acute Lymphoblastic Leukemia Using Dasatinib
ULKCMLN	☐	☑	☐	*Tests clarified*	Treatment of Chronic Myeloid Leukemia Using Nilotinib
ULUAVCRIZ	☑	☐	☐	*Implementation date added*	Second-Line Treatment of ALK-Positive Advanced Non-Small Cell Lung Cancer (NSCLC) with Crizotinib
ULUAVPMTN	☑	☐	☐	*Eligibility revised*	Maintenance Therapy of Advanced Non-Small Cell Lung Cancer (NSCLC) With Pemetrexed
ULUAVPP	☑	☐	☐	*Eligibility revised*	First-Line Treatment of Advanced Non-Small Cell Lung Cancer with Platinum and Pemetrexed
LYALEM	☑	☑	☐	*Eligibility revised, TALLman lettering and lower case drug name formatted*	Treatment with Subcutaneous or Intravenous Alemtuzumab for Fludarabine-Refractory B-Chronic Lymphocytic Leukemia (B-CLL) or with Intravenous Alemtuzumab for Previously Untreated T-Prolymphocytic Leukemia (T-PLL)
ULYBEND	☑	☑	☐	*Diluent volume clarified*	Treatment of Non-Hodgkin Lymphoma with Bendamustine
ULYBENDR	☑	☑	☐	*Diluent volume clarified*	Treatment of Non-Hodgkin Lymphoma with Bendamustine and riTUXimab
ULYCLLBEND	☑	☑	☐	*Diluent volume clarified*	Treatment of Relapsed Chronic Lymphocytic Leukemia (CLL) with Bendamustine
LYCHOPR	☐	☑	☐	*Space to complete total number of cycles added*	Treatment of Lymphoma with DOXOrubicin, Cyclophosphamide, vinCRIStine, Prednisone and riTUXimab
LYFLUDR	☑	☐	☐	*Protocol title revised*	Treatment of Chronic Lymphocytic Leukemia or Prolymphocytic Leukemia and Relapsed Indolent Lymphoma with Fludarabine and riTUXimab

REVISED PROTOCOLS, PPPOS AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED):					
CODE	**Protocol**	**PPPO**	**Patient Handout**	**Changes**	**Protocol Title**
ULYRICE	☑	☐	☐	*CARBOplatin diluent revised*	Treatment of Relapsed or Refractory Advanced Stage Aggressive B-Cell Non-Hodgkin's Lymphoma with Ifosfamide, CARBOplatin, Etoposide and riTUXimab
UMYLENDEX	☑	☑	☐	*Liver function tests added, hepatotoxicity precautions and reference added*	Multiple Myeloma Using Lenalidomide with Dexamethasone
SAVAC	☑	☐	☐	*Minor typo corrected*	Adjuvant Therapy for Newly Diagnosed Ewing's Sarcoma/Peripheral Neuroectodermal Tumour (PNET) or Rhabdomyosarcoma Using vinCRIStine, DOXOrubicin and Cyclophosphamide
SAVACM	☑	☐	☐	*Minor typo corrected*	Summary for Adjuvant Therapy for Newly Diagnosed Ewing's Sarcoma/Peripheral Neuroectodermal Tumour (PNET) or Rhabdomyosarcoma with Pelvic Primaries or Chemotherapy Induced Hematuria Using vinCRIStine, DOXOrubicin, Cyclophosphamide and Mesna

Website Resources and Contact Information

Website Resources	www.bccancer.bc.ca
Systemic Therapy Update	www.bccancer.bc.ca/HPI/ChemotherapyProtocols/stupdate
Reimbursement & Forms: Benefit Drug List, Class II, Compassionate Access Program	www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Forms
Cancer Drug Manual	www.bccancer.bc.ca/cdm
Cancer Management Guidelines	www.bccancer.bc.ca/CaMgmtGuidelines
Cancer Chemotherapy Protocols, Pre-printed Orders, Protocol Patient Handouts	www.bccancer.bc.ca/ChemoProtocols
Systemic Therapy Program Policies	www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Policies
CON Pharmacy Educators	http://www.bccancer.bc.ca/HPI/Pharmacy/ContactUs.htm

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Library/Cancer Information	604.675.8003 Toll Free 888.675.8001 x 8003		requests@bccancer.bc.ca
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OSCAR	888.355.0355	604.708.2051	oscar@bccancer.bc.ca
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BCCA-Abbotsford Centre	604.851.4710 Toll Free 877.547.3777		
BCCA-Centre for the North	250.645.7300 Toll Free 888.775.7300		
BCCA-Fraser Valley Centre	604.930.2098 Toll Free 800.523.2885		
BCCA-Sindi Ahluwalia Hawkins Centre for the Southern Interior	250.712.3900 Toll Free 888.563.7773		
BCCA-Vancouver Centre	604.877.6000 Toll Free 800.663.3333		
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