

## For Health Professionals Who Care for Cancer Patients

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## Editor's Choice

### New Programs

Effective 01 May 2020, 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.

#### Breast

**Neoadjuvant Carboplatin for Locally Advanced, Triple-Negative Breast Cancer (BRLACTWAC)** — The Provincial Systemic Therapy Program has approved the addition of carboplatin to the standard taxane-anthracycline neoadjuvant chemotherapy regimens, for patients with stage II and higher triple-negative breast cancer. This regimen consists of carboplatin (given every 3 weeks) in combination with weekly paclitaxel, followed by doxorubicin-cyclophosphamide (AC given every 2 or 3 weeks). Filgrastim support is available for the dose-dense AC option. This is the first BC Cancer-approved regimen specific to the triple-negative population. In the phase III BrightNess trial, the addition of carboplatin to paclitaxel, followed by doxorubicin-cyclophosphamide, was associated with greater pathologic complete response (pCR 58% vs. 31%), a surrogate marker of long-term clinical outcomes.<sup>1</sup> Patients treated with carboplatin had a higher incidence of grade 3 or 4 treatment-emergent adverse events in both the paclitaxel-based treatment segment (68% vs 15%) and subsequent doxorubicin-cyclophosphamide segment (56% vs 39%). The most common overall grade 3 or 4 adverse events were neutropenia, anemia and thrombocytopenia. Patients treated with carboplatin were more likely to experience febrile neutropenia in the subsequent doxorubicin-cyclophosphamide treatment segment (17% vs 5%).

## Genitourinary

**Apalutamide for Non-Metastatic Castration-Resistant Prostate Cancer (UGUPAPA)** — The BC Cancer Genitourinary Tumour Group is introducing apalutamide, an oral nonsteroidal androgen receptor inhibitor. Patients with castration-sensitive prostate cancer are routinely treated with androgen-deprivation therapy (ADT). A proportion of these patients will develop treatment resistance in the absence of metastases – this is termed non-metastatic castration-resistant prostate cancer (nmCRPC). Patients with nmCRPC and a prostate-specific antigen (PSA) doubling time of less than 10 months are at a high risk of developing metastatic disease despite continuation of ADT; thus apalutamide fills a need in this patient population.<sup>2</sup> A BC Cancer Compassionate Access Program (CAP) approval is required. Note that patients whose disease progresses on apalutamide (UGUPAPA) are not eligible to receive enzalutamide (UGUPENZ) in the metastatic setting.

Approval of this new treatment program is based on the phase III SPARTAN trial which compared apalutamide plus ADT to placebo plus ADT in patients with nmCRPC.<sup>3</sup> Apalutamide plus ADT was associated with an improvement in the median metastasis-free survival (mMFS 40.5 mo vs. 16.2 mo, HR 0.28, 95% CI 0.23-0.35). Adverse events occurring at a higher rate with apalutamide included fatigue (30.4% vs. 21.1%), hypertension (24.8% vs. 19.8%), rash (23.8% vs. 5.5%), falls (15.6% vs. 9.0%), fracture (11.7% vs 6.5%) and hypothyroidism (8.1% vs. 2.0%). In particular, the proportion of patients with grade 3 or 4 rash was higher in the apalutamide arm (5.2% vs 0.3%); dose modification recommendations for rash are outlined in UGUPAPA.

### References

1. Loibl S, O'Shaughnessy J, Untch M, et al. Addition of the PARP inhibitor veliparib plus carboplatin or carboplatin alone to standard neoadjuvant chemotherapy in triple-negative breast cancer (BrighTNess): a randomised, phase 3 trial. *Lancet Oncol* 2018; 19: 497–509. [https://doi.org/10.1016/S1470-2045\(18\)30111-6](https://doi.org/10.1016/S1470-2045(18)30111-6)
2. Pan-Canadian Oncology Drug Review (pCODR) Expert Review Committee (pERC). Final recommendation for apalutamide (Erleada®) for non-metastatic castration-resistant prostate cancer. 01 November 2018.
3. Smith MR, Saad F, Chowdhury S, et al. Apalutamide treatment and metastasis-free survival in prostate cancer. *N Engl J Med* 2018;378(15):1408-1418. <https://doi.org/10.1056/NEJMoa1715546>

## Drug Update

### PharmaCare Update – Anticoagulants

Last month, BC PharmaCare began implementing changes to ensure efficient access to medications and promote patient safety during the COVID-19 pandemic. The low-molecular weight heparins (LMWHs), dalteparin and tinzaparin, were identified as first-line treatment options for venous thromboembolism (VTE) in cancer patients, without the usual requirement of a prior trial of warfarin; this avoids the need for more frequent lab testing that is typically required at the initiation of warfarin, thus reducing travel for patients during the COVID-19 pandemic. The rationale to reduce lab testing is consistent with the [BC Cancer Provincial Cancer Clinical Management Guidelines in Pandemic Situation \(COVID-19\)](#).

Effective 30 March 2020, BC PharmaCare's Special Authority criteria for direct-acting anticoagulants (DOACs) were revised for the duration of the COVID-19 pandemic. Patients initiating anticoagulation therapy with DOACs for the prevention of atrial fibrillation-associated ischemic stroke, or for the treatment of VTE (in the general population), are also not required to have a prior trial of warfarin. This change is summarized in the 01 April 2020 issue of the [BC PharmaCare Newsletter](#).

Lastly, BC PharmaCare is extending the Special Authority coverage window for select drugs (including filgrastim, dalteparin, tinzaparin) to 01 October 2020. The full listings of affected drugs can be found in the 26 March 2020 and 01 April 2020 issues of the [BC PharmaCare Newsletter](#).

## Manufacturer Patient Assistance Programs

The listing of patient assistance programs offered by pharmaceutical manufacturers has been updated and can be accessed on the BC Cancer website under Health Professionals > Systemic Therapy > [Reimbursement & Forms](#).

## Drug Shortages

The following are updates of drug supply shortages in BC. Full details about new, updated or resolved drug shortages, including recommended treatment alternatives, can be found in the *Briefing Notes* and email communications previously circulated to BC Cancer and the Community Oncology Network (CON).

### New

#### **Alemtuzumab**

*(Adapted from BC Cancer Briefing Note 30Apr2020)*

It is anticipated that there will be a 4-month stock-out on alemtuzumab from 01 June to 01 September 2020, due to a production interruption.

Alemtuzumab is funded under the BC Cancer protocol code LYALEM for use in patients with fludarabine-refractory B-chronic lymphocytic leukemia (B-CLL) or in patients with previously untreated T-prolymphocytic leukemia (T-PLL). Alemtuzumab supply is managed through the Clinigen MabCampath Distribution Program. Prescribers must secure patient-specific supplies by applying directly to the distribution program, *prior to starting treatment*. BC Cancer centres do not currently have any alemtuzumab on hand.

If alemtuzumab is unavailable, the following alternative treatment protocols should be considered:

LYALEM Protocol	Therapeutic Alternatives
B-CLL indication	LYCLLBEND LYCLLBENDR LYCLLCVPR ULYIBRU ULYIDELAR ULYVENETO ULYVENETOR
T-PLL indication	Consult Lymphoma & Myeloma Tumour Group

#### **Anagrelide**

*(Adapted from BC Cancer Briefing Note 30Apr2020)*

There is a potential shortage of anagrelide capsules at the level of the Canadian suppliers; anagrelide resupply is expected July 2020. A temporary increase in anagrelide usage may be resulting from the ongoing hydroxyurea drug shortage, which is expected to resolve by the end of April 2020.

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## Drug Shortages

Anagrelide is funded by BC Cancer for patients with thrombocytosis secondary to myeloproliferative disorder (LKANAG) who have had an inadequate response to or are intolerant of hydroxyurea and/or interferon. There are limited treatment options for this patient population, and consultation with the Leukemia/BMT Tumour Group is recommended. To conserve anagrelide supplies, BC Cancer centers and CON sites may reduce the total quantity dispensed to a 1-month supply.

## Updated

### Hydroxyurea

*(Adapted from BC Cancer Briefing Note Update 20Apr2020)*

It is reported that hydroxyurea supplies will become available at the end of April 2020, with supplies expected to be very limited until May 2020. Until supplies are available, BC Cancer centres and CON sites are advised to dispense only a 1- to 2-week supply to ensure that there is sufficient drug for all currently-treated patients.

## Cancer Drug Manual<sup>©</sup>

All BC Cancer Drug Manual<sup>©</sup> documents can be accessed from the [Cancer Drug Manual<sup>©</sup>](#) home page on the BC Cancer website.

## New Documents

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

The **Abemaciclib Interim Monograph** and **Patient Handout** have been developed with expert review provided by Dr. Angela Chan (medical oncologist) and Khushminder Rai (clinical pharmacist) of the BC Cancer Breast Tumour Group. Abemaciclib is an orally administered inhibitor of cyclin-dependent kinases 4 and 6 (CDK 4/6 inhibitor) and is used in the treatment of breast cancer. Unlike palbociclib and ribociclib, abemaciclib is administered on a continuous dosing schedule, without the need for a scheduled dose interruption with every cycle.

Highlights from these documents include:

- diarrhea is experienced in up to 90% of patients during the first month of treatment; early intervention with antidiarrheal medication is recommended
- fatigue, neutropenia, and nausea are frequently reported side effects

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

The **Lurbinectedin Interim Monograph** has been developed. Lurbinectedin is a selective inhibitor of oncogenic transcription; it binds preferentially to guanines located in DNA gene promoters, leading to tumour cell apoptosis. The usual dose in the treatment of small cell lung cancer is 3.2 mg/m<sup>2</sup> IV given on day 1 of a three-week cycle. Lurbinectedin is available only through the Health Canada Special Access Programme.

Highlights from this document include:

- reversible myelosuppression is the most frequent and serious adverse effect; dose reduction and secondary prophylaxis with filgrastim may be required
- concurrent use of aprepitant or other neurokinin-1 receptor antagonists (*NK-1 RAs*) may cause more severe and prolonged myelosuppression and should be avoided (note lurbinectedin has low emetogenic potential and *NK-1 RAs* are unlikely to be required)

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

### Revised Documents

Highlights of key changes are listed below:

#### **Apalutamide Monograph and Patient Handout**

*Cautions:* added information pertaining to cardiac risk factors and falls/fracture risk assessment

*Dosage Guidelines:* updated with new BC Cancer protocol

#### **Durvalumab Monograph**

*Dosage Guidelines:* updated with new BC Cancer protocol

#### **Panitumumab Chemotherapy Preparation and Stability Chart**

*(Final) Product:* updated dose-dependent preparation instructions (dose cut-off for the 100 mL bag is no longer required)

#### **Pembrolizumab Monograph**

*Dosage Guidelines:* updated with new BC Cancer protocol

## Systemic Therapy Update Editorial Board

### Membership Update

The Systemic Therapy Update Editorial Board would like to bid farewell to **Jennifer Pesut** (Oncology Nurse Educator, Professional Practice Nursing, BC Cancer) as she steps down from the Board to pursue other opportunities. Thank you for your contributions!

The Editorial Board would also like to welcome **Jeevan Dosanjh** (Oncology Nurse Educator, Professional Practice Nursing, BC Cancer) to the Board. Welcome Jeevan!

## Benefit Drug List

### New Programs

Effective 01 May 2020, the following new treatment programs have been added to the BC Cancer [Benefit Drug List](#):

Protocol Title	Protocol Code	Benefit Status
Neoadjuvant Therapy for Triple-Negative Breast Cancer using <b>Carboplatin</b> and <b>Weekly Paclitaxel</b> Followed by <b>Doxorubicin</b> and <b>Cyclophosphamide</b>	<b>BRLACTWAC</b>	Class I
Therapy of Non-Metastatic Castration-Resistant Prostate Cancer using <b>Apalutamide</b>	<b>UGUPAPA</b>	Restricted
Treatment of Acute Lymphoblastic Leukemia and Lymphoblastic Lymphoma using <b>Pegaspargase (Oncaspar®)</b>	<b>LKNOS, LYNOS</b>	Class I
Treatment with <b>Bevacizumab</b> as a Single Agent or in Combination with Chemotherapy for Pediatric Patients with Low-Grade Glioma Progressing after First-Line Chemotherapy	<b>Pediatric</b>	Class I
Treatment of Pediatric Patients with Relapsed Hodgkin Lymphoma with a Combination of <b>Ifosfamide</b> , <b>Mesna</b> , <b>Gemcitabine</b> and <b>Vinorelbine (IGEV)</b>	<b>Pediatric</b>	Class I

## Benefit Drug List

### Deleted Programs

Effective 01 May 2020, the following treatment programs have been deleted from the BC Cancer [Benefit Drug List](#):

Protocol Title	Protocol Code	Benefit Status
Palliative Therapy for Metastatic or Locally Advanced Gastric or Esophagogastric Cancer using <b>Epirubicin</b> , <b>Oxaliplatin</b> and <b>Capecitabine</b>	<b>GIGAVEOCAP</b>	Deleted <i>(previously replaced by GIGAVCOX)</i>
Palliative Therapy for Metastatic or Locally Advanced Gastric or Esophagogastric Cancer using <b>Epirubicin</b> , <b>Oxaliplatin</b> and <b>Infusional Fluorouracil</b>	<b>GIGAVEOF</b>	Deleted <i>(previously replaced by GIGAVFFOX)</i>
Adjuvant Therapy of High-Risk Malignant Melanoma with <b>High-Dose Interferon (HDIFN) Alfa-2b</b>	<b>SMAJIFN</b>	Deleted

## 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 approval are prefixed with the letter **U**.

### NEW Protocols, PPPOs and Patient Handouts (*new documents checked* )

Code	Protocol Title	Protocol	PPPO	Handout
<b>BRLACTWAC</b>	Neoadjuvant Therapy for Triple-Negative Breast Cancer using Carboplatin and Weekly Paclitaxel Followed by Doxorubicin and Cyclophosphamide	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
<b>UGUPAPA</b>	Therapy of Non-Metastatic Castration-Resistant Prostate Cancer using Apalutamide	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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

Code	Protocol Title	Protocol	PPPO	Handout
<b>BR   Breast</b>				
<b>BRAJAC</b>	Adjuvant Therapy for Breast Cancer using Doxorubicin and Cyclophosphamide	----	<i>Antiemetics updated</i>	----
<b>BRAJACT</b>	Neoadjuvant or Adjuvant Therapy for Breast Cancer using Doxorubicin and Cyclophosphamide Followed by Paclitaxel	----	<i>Antiemetics updated</i>	----
<b>BRAJACTG</b>	Neoadjuvant or Adjuvant Therapy for Breast Cancer using Dose-Dense Therapy: Doxorubicin and Cyclophosphamide Followed by Paclitaxel	----	<i>Antiemetics updated</i>	----
<b>BRAJACTT</b>	Neoadjuvant or Adjuvant Therapy for Breast Cancer using Doxorubicin and Cyclophosphamide Followed by Paclitaxel and Trastuzumab	----	<i>Antiemetics updated</i>	----
<b>BRAJACTTG</b>	Neoadjuvant or Adjuvant Therapy for Breast Cancer using Dose-Dense Therapy: Doxorubicin and Cyclophosphamide Followed by Paclitaxel and Trastuzumab	----	<i>Antiemetics updated</i>	----
<b>BRAJACTW</b>	Neoadjuvant or Adjuvant Therapy for Early Breast Cancer using Doxorubicin and Cyclophosphamide Followed by Weekly Paclitaxel	----	<i>Antiemetics updated</i>	----
<b>BRAJDAC</b>	Neoadjuvant or Adjuvant Therapy for Breast Cancer using Cyclophosphamide, Doxorubicin and Docetaxel	----	<i>Antiemetics updated</i>	----

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

Code	Protocol Title	Protocol	PPPO	Handout
<b>BRAJFEC</b>	Adjuvant Therapy for Breast Cancer using Fluorouracil, Epirubicin and Cyclophosphamide	-----	<i>Antiemetics updated</i>	-----
<b>BRAJFCD</b>	Neoadjuvant or Adjuvant Therapy for Breast Cancer using Fluorouracil, Epirubicin, Cyclophosphamide and Docetaxel	-----	<i>Antiemetics updated</i>	-----
<b>BRAJFCDT</b>	Neoadjuvant or Adjuvant Therapy for Breast Cancer using Fluorouracil, Epirubicin and Cyclophosphamide Followed by Docetaxel and Trastuzumab	-----	<i>Antiemetics updated</i>	-----
<b>BRAVAC</b>	Palliative Therapy for Metastatic Breast Cancer using Doxorubicin and Cyclophosphamide	-----	<i>Antiemetics updated</i>	-----
<b>BRLAACD</b>	Treatment of Locally Advanced Breast Cancer using Doxorubicin and Cyclophosphamide Followed by Docetaxel	-----	<i>Antiemetics updated</i>	-----
<b>BRLAACDT</b>	Treatment of Locally Advanced Breast Cancer using Doxorubicin and Cyclophosphamide Followed by Docetaxel and Trastuzumab	-----	<i>Antiemetics updated</i>	-----
<b>BRLATACG</b>	Neoadjuvant Therapy for Breast Cancer using Dose-Dense Therapy: Paclitaxel Followed by Doxorubicin and Cyclophosphamide	-----	<i>Antiemetics updated</i>	-----
<b>BRLATWAC</b>	Neoadjuvant Therapy for Locally Advanced Breast Cancer using Weekly Paclitaxel Followed by Doxorubicin and Cyclophosphamide	-----	<i>Antiemetics updated</i>	-----
<b>GI   Gastrointestinal</b>				
<b>GIPGEMABR</b>	First-Line Treatment of Locally Advanced and Metastatic Pancreatic Cancer with Paclitaxel-Nab (Abraxane®) and Gemcitabine	<i>Exclusions updated</i>	-----	-----
<b>GU   Genitourinary</b>				
<b>UGUPABI</b>	Palliative Therapy for Metastatic Castration-Resistant Prostate Cancer using Abiraterone and Prednisone	<i>Eligibility updated</i>	-----	-----
<b>UGUPENZ</b>	Palliative Therapy for Metastatic Castration-Resistant Prostate Cancer using Enzalutamide	<i>Eligibility, Exclusions and Tests updated; Treatment duration clarified</i>	-----	-----
<b>LK   Leukemia</b>				
<b>ULKBLIN</b>	Treatment of Philadelphia Chromosome (Ph)-Positive or Ph-Negative Refractory or Relapsed Pre-B-Cell Acute Lymphoblastic Leukemia with Blinatumomab	<i>Protocol title and Eligibility updated</i>	-----	-----



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

Code	Protocol Title	Protocol	PPPO	Handout
<b>ULKMDSA</b>	Therapy of Myelodysplastic Syndrome and Acute Myeloid Leukemia using Azacitidine	<i>Pre-treatment metrics and Tests updated (urea and albumin deleted)</i>	----	----
<b>SA   Sarcoma</b>				
<b>SAIME</b>	Etoposide, Ifosfamide-Mesna for Use in Sarcomas	----	<i>Optional post-hydration added; AST replaced by ALT</i>	----
<b>SC   Supportive Care</b>				
<b>SCDRUGRX</b>	Management of <b>Infusion-Related Hypersensitivity Reactions to Systemic Therapy Chemotherapeutic Agents</b>	<i>Protocol title, Contact Physician, Treatment and References updated</i>	----	----
<b>SM   Skin and Melanoma</b>				
<b>USMAVDAB</b>	Treatment of BRAF V600 Mutation-Positive Unresectable or Metastatic Melanoma using Dabrafenib	<i>Institutional name, Contact Physician Eligibility, Tests and References updated</i>	----	----
<b>USMAVDT</b>	Treatment of BRAF V600 Mutation-Positive Unresectable or Metastatic Melanoma using Dabrafenib and Trametinib	<i>Institutional name, Contact Physician Eligibility, Tests and References updated</i>	----	----
<b>USMAVTRA</b>	Treatment of BRAF V600 Mutation-Positive Unresectable or Metastatic Melanoma using Trametinib	<i>Institutional name, Contact Physician Eligibility, Tests and References updated</i>	----	----
<b>USMAVVC</b>	Treatment of BRAF V600 Mutation-Positive Unresectable or Metastatic Melanoma using Vemurafenib and Cobimetinib	<i>Institutional name, Contact Physician Eligibility and Tests updated</i>	----	----
<b>USMAVVEM</b>	Treatment of BRAF V600 Mutation-Positive Unresectable or Metastatic Melanoma using Vemurafenib	<i>Institutional name, Contact Physician Eligibility and Tests updated</i>	----	----

## Resources and Contact Information

Resource	Phone	Email / Toll Free / Fax
Systemic Therapy Update: <a href="http://www.bccancer.bc.ca/health-professionals/clinical-resources/systemic-therapy/systemic-therapy-update">www.bccancer.bc.ca/health-professionals/clinical-resources/systemic-therapy/systemic-therapy-update</a>		
Systemic Therapy Update Editor	604-877-6000 x 672649	<a href="mailto:bulletin@bccancer.bc.ca">bulletin@bccancer.bc.ca</a>
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	<a href="mailto:druginfo@bccancer.bc.ca">druginfo@bccancer.bc.ca</a> <a href="mailto:nbadry@bccancer.bc.ca">nbadry@bccancer.bc.ca</a> <a href="mailto:rxchemocert@bccancer.bc.ca">rxchemocert@bccancer.bc.ca</a> <a href="mailto:nursinged@bccancer.bc.ca">nursinged@bccancer.bc.ca</a>
CAP – Compassionate Access Program	604-877-6277	<a href="mailto:cap_bcca@bccancer.bc.ca">cap_bcca@bccancer.bc.ca</a> fax 604-708-2026
OSCAR – Online System for Cancer Drugs Adjudication and Reimbursement	888-355-0355	<a href="mailto:oscar@bccancer.bc.ca">oscar@bccancer.bc.ca</a> fax 604-708-2051
Library/Cancer Information	604-675-8003	toll free 888-675-8001 x 8003 <a href="mailto:requests@bccancer.bc.ca">requests@bccancer.bc.ca</a>
Library Document Delivery	604-675-8002	<a href="mailto:requests@bccancer.bc.ca">requests@bccancer.bc.ca</a>
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	<a href="mailto:mclin@bccancer.bc.ca">mclin@bccancer.bc.ca</a> <a href="mailto:BCcancerPPNAdmin@ehcnet.phsa.ca">BCcancerPPNAdmin@ehcnet.phsa.ca</a> <a href="mailto:mclin@bccancer.bc.ca">mclin@bccancer.bc.ca</a>
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: <a href="mailto:bulletin@bccancer.bc.ca">bulletin@bccancer.bc.ca</a>		

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