



For Health Professionals Who Care For Cancer Patients

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EDITOR'S CHOICE

NEW PROGRAMS

The BCCA Provincial Systemic Therapy Program has approved the following programs effective 1 December 2015:

Lung:

Crizotinib for First-Line Treatment of ALK-Positive Advanced Non-Small Cell Lung Cancer (NSCLC) (ULUAVCRIZF) – Previously, BCCA had approved crizotinib for patients with confirmed anaplastic lymphoma kinase (ALK)-positive tumours whose disease has progressed after prior platinum-based chemotherapy. Based on results from the recent PROFILE 1014 trial, BCCA has now approved crizotinib in the first-line setting.¹

In this phase III study, 343 patients with previously untreated, advanced ALK-positive nonsquamous NSCLC were randomized to oral crizotinib 250 mg twice daily versus standard chemotherapy (pemetrexed with platinum therapy). Crizotinib was associated with improved median progression-free survival (10.9 months vs. 7.0 months, with HR for progression or death of 0.45), and objective response rates (74% vs. 45%). Median overall survival was not reached in either treatment group. Crizotinib was also associated with greater improvement in quality of life as well as lung cancer symptoms (e.g. dyspnea, cough, pain, insomnia). The most common adverse events with crizotinib were vision disorders (71%), diarrhea (61%), edema (49%), nausea (56%), vomiting (46%) and constipation (43%).

Lymphoma/Multiple Myeloma:

Ibrutinib for Relapsed or Refractory Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic

EDITOR'S CHOICE

Lymphoma (SLL) (ULYIBRU) – Ibrutinib is now approved for patients with CLL or SLL who have received at least one previous therapy. The program was approved based on results from the RESONATE trial that included 391 patients with CLL or SLL who had received at least one previous therapy, and who were not appropriate candidates for purine analog-based therapy.² Ibrutinib was associated with increased progression free survival (median not reached, HR 0.22) and overall survival (median not reached, HR 0.43) compared to ofatumumab, an agent shown to be effective in relapsed CLL. Additional information about ibrutinib's pharmacology and toxicities can be found in the [Cancer Drug Manual](#) section of the current Systemic Therapy Update issue. All patients who were previously enrolled in the Janssen's YOU&i™ Support Program and who meet the ULYIBRU eligibility criteria will require a BCCA Compassionate Access Program (CAP) approval.

References:

1. BJ Solomon, T Mok, DW Kim, et al. First-line crizotinib versus chemotherapy in ALK-positive lung cancer. *N Engl J Med* 2014;371:2167-2177.
2. JC Byrd, JR Brown, S O'Brien et al. Ibrutinib versus ofatumumab in previously treated chronic lymphoid leukemia. *N Engl J Med* 2014;371:213-23.

DRUG UPDATE

BACILLUS CALMETTE-GUÉRIN (BCG) VACCINE DRUG SHORTAGE RESOLVED

Effective 9 November 2015, the national drug shortage of the Bacillus Calmette-Guérin (BCG) vaccine (OncoTICE®) has been resolved. Pharmacy departments may now resume normal stock acquisition process through M^cKesson Canada or Merck Canada Inc.

The BCG vaccine is considered the treatment of choice for superficial transitional cell bladder cancer, with mitomycin as a standard alternative. At the time of the BCG vaccine shortage, which also led to a shortage of mitomycin, the BCCA provided temporary funding for other intravesical agents (i.e. epirubicin, doxorubicin, gemcitabine and docetaxel). Patients who are presently receiving these alternative agents may continue to have these agents funded by the BCCA. For further information on the temporary funding of the alternative intravesical agents, please refer to the [March 2015](#) issue of the Systemic Therapy Update.

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NEW MONOGRAPHS AND PATIENT HANDOUTS

Ibrutinib Monograph and Patient Handout have been developed with expert review provided by Dr. Laurie Sehn (Medical Oncologist, BCCA Lymphoma Tumour Group) and Linda Hamata (Pharmacist, BCCA Lymphoma Tumour Group). Ibrutinib is an inhibitor of Bruton's tyrosine kinase and has demonstrated activity in B-cell malignancies, including CLL.

Ibrutinib is administered orally once daily. Common side effects include diarrhea, pyrexia, myelosuppression, infections and hyperuricemia. A temporary lymphocytosis can develop within the first few weeks of treatment and is not an indication of disease progression in the absence of other clinical

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findings. Hemorrhagic events are also a common occurrence and caution should be used in patients taking anticoagulants or medications that inhibit platelet function. Ibrutinib should be held for 3 to 7 days pre- and post-surgery to minimize the risk of bleeding.

BENEFIT DRUG LIST

NEW PROGRAMS

The following programs have been added to the BCCA [Benefit Drug List](#) effective 1 December 2015:

Protocol Title	Protocol Code	Benefit Status
First-Line Treatment of ALK-Positive Advanced Non-Small Cell Lung Cancer (NSCLC) with Crizotinib	ULUAVCRIZF	Restricted
Treatment of Relapsed or Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma using Ibrutinib	ULYIBRU	Restricted

REVISED PROGRAMS

The following programs have been revised on the BCCA [Benefit Drug List](#) effective 1 December 2015:

Protocol Title	Protocol Code	Benefit Status
Palliative Therapy for Metastatic Breast Cancer Using Pertuzumab, Trastuzumab, and DOCEtaxel as First-Line Treatment for Advanced Breast Cancer	BRAVPTRAD	Class II (Previously Restricted)
Hyperthermic Intraperitoneal Chemotherapy (HIPEC) for Patients with Peritoneal Mesothelioma Using DOXOrubicin, CISplatin and PACLitaxel	GIPMHIPEC	Class I (Previously Restricted)

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 BCCA Compassionate Access Program approval are prefixed with the letter "U".

NEW PROTOCOLS, PPPOs AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED):

CODE	Protocol	PPPO	Patient Handout	Protocol Title
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NEW PROTOCOLS, PPPOs AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED):				
CODE	Protocol	PPPO	Patient Handout	Protocol Title
ULUAVCRIZF	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	First-Line Treatment of ALK-Positive Advanced Non-Small Cell Lung Cancer (NSCLC) with Crizotinib
ULYIBRU	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Treatment of Relapsed or Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma using Ibrutinib

REVISED PROTOCOLS, PPPOs AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED):					
CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
BRAVPTRAD	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Revised Protocol Code, Eligibility Criteria, and laboratory test requirements; clarified duration of pertuzumab infusion and observation time for cycle 2 and onward</i>	Palliative Therapy for Metastatic Breast Cancer Using Pertuzumab, Trastuzumab, and DOCETaxel as First-Line Treatment for Advanced Breast Cancer
GIGAVCC	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Protocol title and eligibility updated</i>	Palliative Therapy for Metastatic or Locally Advanced Gastric or Gastroesophageal Junction Adenocarcinoma using CISplatin and Capecitabine
GIPMHIPEC	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Requirement for CAP approval deleted, protocol code updated</i>	Hyperthermic Intraperitoneal Chemotherapy (HIPEC) for Patients with Peritoneal Mesothelioma Using DOXOrubicin, CISplatin and PACLitaxel
ULKATOATRA	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Prophylaxis for HSV and VZV seropositive patients updated</i>	First-Line Induction and Consolidation Therapy of Acute Promyelocytic Leukemia Using Arsenic Trioxide and Tretinoin
ULKATOP	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Prophylaxis for HSV and VZV seropositive patients updated</i>	First-Line Induction and Consolidation Therapy of Acute Promyelocytic Leukemia Using Arsenic Trioxide, Tretinoin and DAUNOrubicin
ULKATOR	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Prophylaxis for HSV and VZV seropositive patients updated</i>	Induction and Consolidation Therapy of Relapsed Acute Promyelocytic Leukemia Using Arsenic Trioxide
ULUAVCRIZ	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Eligibility clarified</i>	Second-Line Treatment of ALK-Positive Advanced Non-Small Cell Lung Cancer with Crizotinib
UMYBORMTN	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Return appointment clarified</i>	Maintenance Therapy of Multiple Myeloma Using Bortezomib for Patients with the High-Risk Chromosome Abnormality
UMYBORPRE	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Return lab tests clarified</i>	Treatment of Multiple Myeloma Using Bortezomib, Dexamethasone with or without Cyclophosphamide as Induction Pre-Stem Cell Transplant

REVISED PROTOCOLS, PPPOs AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED):

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
UMYBORREL	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Return lab tests clarified</i>	Treatment of Relapsed Multiple Myeloma Using Bortezomib, Dexamethasone with or without Cyclophosphamide
UMYMPBOR	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Return lab tests clarified</i>	Treatment of Multiple Myeloma using Melphalan, Prednisone and Weekly Bortezomib with the Option of Substituting Cyclophosphamide for Melphalan
SAAVGI	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Eligibility, Blood work for dose modifications, and Drug Interactions revised</i>	Treatment of Advanced C-Kit Positive and C-Kit Negative Gastrointestinal Stromal Cell Tumours Using Imatinib
SAAVGIDD	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Eligibility, blood work for dose modifications, and Drug Interactions revised</i>	Treatment of Advanced c-Kit Positive Gastrointestinal Stromal Cell Tumors (GIST) Using 800 mg Dosing of Imatinib
USMAVFIPI	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Weekly nursing assessments added under Tests section</i>	First-Line Treatment of Unresectable or Metastatic Melanoma Using Ipilimumab
USMAVIPI	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Weekly nursing assessments added under Tests section</i>	Treatment of Unresectable or Metastatic Melanoma Using Ipilimumab

WEBSITE RESOURCES AND CONTACT INFORMATION

WEBSITE RESOURCES	www.bccancer.bc.ca
Systemic Therapy Update	www.bccancer.bc.ca/health-professionals/professional-resources/systemic-therapy/systemic-therapy-update
Reimbursement & Forms: Benefit Drug List, Class II, Compassionate Access Program	www.bccancer.bc.ca/health-professionals/professional-resources/systemic-therapy
Cancer Drug Manual	www.bccancer.bc.ca/health-professionals/professional-resources/cancer-drug-manual
Cancer Management Guidelines	www.bccancer.bc.ca/health-professionals/professional-resources/cancer-management-guidelines
Cancer Chemotherapy Protocols, Pre-printed Orders, Protocol Patient Handouts	www.bccancer.bc.ca/health-professionals/professional-resources/chemotherapy-protocols
Systemic Therapy Program Policies	www.bccancer.bc.ca/health-professionals/professional-resources/systemic-therapy
CON Pharmacy Educators	www.bccancer.bc.ca/health-professionals/professional-resources/pharmacy

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Oncology Drug Information	604-877-6275		druginfo@bccancer.bc.ca
Education Resource Nurse	604-877-6000 x 672638		nursinged@bccancer.bc.ca
Library/Cancer Information	604-675-8003 Toll Free 888-675-8001 x 8003		requests@bccancer.bc.ca
Pharmacy Professional Practice	604-877-6000 x 672247		mclin@bccancer.bc.ca
Nursing Professional Practice	604-877-6000 x 672623		ilundie@bccancer.bc.ca
OSCAR	888-355-0355	604-708-2051	oscar@bccancer.bc.ca
Compassionate Access Program (CAP)	604-877-6277	604-708-2026	cap_bcca@bccancer.bc.ca
Pharmacy Chemotherapy Certification	250-712-3900 x 686741		rxchemocert@bccancer.bc.ca
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		
BCCA-Vancouver Island Centre	250-519-5500 Toll Free 800-670-3322		

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