

## For Health Professionals Who Care for Cancer Patients

### Inside This Issue:

#### Editor's Choice

**New Programs** Abiraterone and Prednisone for Metastatic Castration-Sensitive Prostate Cancer (UGUMCSPABI) | Gilteritinib for Relapsed or Refractory FLT3+ Acute Myeloid Leukemia (ULKAMLGIL) | Fluorouracil Eye Drops for Ocular Malignancies (OCFU) | **Revised Programs** High-Dose Methotrexate, Rituximab and Temozolomide for Primary and Secondary CNS Lymphoma (LYHDMRTEM)

#### Cancer Drug Manual®

**New** Amivantamab | **Revised** Fluorouracil, Gilteritinib, Leucovorin

#### Benefit Drug List

**New** UGUMCSPABI, ULKAMLGIL, OCFU | **Revised** LKGEMOZ, LYHDMRTEM | **Deleted** LYHDMTXP, LYHDMTXR

#### New Protocols, PPPOs & Patient Handouts

**GU** UGUMCSPABI | **LK** ULKAMLGIL | **OC** OCFU

#### Revised Protocols, PPPOs & Patient Handouts

**BR** BRAJPAM, BRAJZOL2, BRAJZOL5, BRAVPAM, BRAVZOL | **GI** GIAVFL, GIAVPG, GIFFIRB, GIFOLFIRI, GIPAVFFIRI, UGIPRRT, GIRAJCOX, GIRAJFFOX | **GU** GUBPWRT | **HN** UHNAVPMBF | **LK** LKGEMOZ | **LY** LYABVD, LYHDMRTEM, LYRITUX | **MO** MOIT | **MY** MYBORPRE, MYPAM, MYZOL | **SA** SAAVGR

#### Resources and Contact Information

### Editor's Choice

#### New Programs

The BC Cancer Provincial Systemic Therapy Program has approved the following new treatment programs effective 01 September 2021. Full details of all treatment programs are available in the [Chemotherapy Protocols](#) section of the BC Cancer website.

#### Genitourinary

##### **Abiraterone and Prednisone for Metastatic Castration-Sensitive Prostate Cancer (UGUMCSPABI) —**

The BC Cancer Genitourinary Group is implementing abiraterone-prednisone for use in patients with metastatic castration-sensitive prostate cancer (mCSPC).<sup>1</sup> Patients with mCSPC are eligible for this treatment program if they are chemotherapy naïve or have received prior docetaxel-containing chemotherapy; in addition, they must have received no prior androgen deprivation therapy (ADT), or received ADT for less than 6 months in the setting of mCSPC. Patients without orchiectomy should be maintained on ADT with LHRH agonist or antagonist while on this treatment program. BC Cancer Compassionate Access Program (CAP) approval is required.

Approval for this treatment program is based on the phase III LATITUDE trial, in which patients were randomized to receive either abiraterone-prednisone or placebo; both groups received ADT.<sup>2</sup> At a planned interim analysis, both the median overall survival (mOS) and the median length of radiographic progression-free survival (PFS) were significantly longer in the abiraterone group (mOS: not reached vs. 34.7 months, HR 0.62, 95% CI 0.51-0.76; radiographic PFS: 33.0 months vs. 14.8 months, HR 0.47, 95% CI 0.39-0.55). Grade 3 mineralocorticoid-related adverse effects occurred at a higher frequency in the abiraterone group, including hypertension (20% vs. 10%) and hypokalemia (10% vs. 1%).

#### Leukemia

**Gilteritinib for Relapsed or Refractory FLT3+ Acute Myeloid Leukemia (ULKAMLGIL)** — The BC Cancer Leukemia/BMT Tumour Group is introducing gilteritinib for patients with relapsed or refractory acute myeloid leukemia with a FMS-like tyrosine kinase 3 (FLT3) mutation.<sup>3</sup> Gilteritinib is a small molecule, multi-targeted oral tyrosine kinase inhibitor with activity in cells that express FLT3. Usual dosing for gilteritinib is 120 mg orally once daily, with dose modifications permitted as necessary for toxicities. BC Cancer CAP approval is required.

Approval for this treatment program is based on the phase III ADMIRAL trial, in which patients received gilteritinib or salvage chemotherapy.<sup>4</sup> Median overall survival was significantly longer in the gilteritinib group (9.3 months vs. 5.6 months, HR 0.64, 95% CI 0.49-0.83). The most common grade 3 or higher adverse events in the gilteritinib group were febrile neutropenia (45.9%), anemia (40.7%) and thrombocytopenia (22.8%). The most common drug-related adverse events leading to the discontinuation of gilteritinib were elevated aspartate aminotransferase level (1.6%), elevated alanine aminotransferase level (1.2%) and pneumonia (1.2%).

#### Ocular

**Fluorouracil Eye Drops for Ocular Malignancies (OCFU)** — The BC Cancer Ocular and Orbital Tumour Group is introducing fluorouracil eye drops for use in patients with ocular malignancies. Fluorouracil joins mitomycin as an additional treatment option for ocular malignancies such as malignant melanoma of the conjunctiva and ocular surface squamous neoplasia (OSSN). Interferon alfa-2b eye drops were also used for this indication until recently, when interferon alfa-2b was discontinued globally. In a study comparing fluorouracil and interferon alfa-2b eye drops, both agents resulted in a high frequency of tumour resolution and low recurrence rates and were effective treatment options for OSSN.<sup>5,6</sup>

#### References

1. CADTH Health Technology Review. Abiraterone acetate for metastatic castration-sensitive prostate cancer. *Canadian Journal of Health Technologies*. 2021;1(5).
2. Fizazi K, Tran N, Fein L, et al. Abiraterone plus prednisone in metastatic, castration sensitive prostate cancer. *N Engl J Med* 2017;377(17):1696-1697. <https://doi.org/10.1056/NEJMoa1704174>
3. Pan-Canadian Oncology Drug Review (pCODR) Expert Review Committee (pERC). Final recommendation for gilteritinib (Xospata®) for acute myeloid leukemia. 20 May 2020.
4. Perl AE, Martinelli G, Cortes JE, et al. Gilteritinib or chemotherapy for relapsed or refractory FLT3-mutated AML. *N Engl J Med* 2019;381(18):1728-1740. <https://doi.org/10.1056/NEJMoa1902688>
5. Venkateswaran N, Mercado C, Galor A, et al. Comparison of topical 5-fluorouracil and interferon alfa-2b as primary treatment modalities for ocular surface squamous neoplasia. *Am J Ophthalmol* 2019;199:216-222.
6. Al Bayyat G, Arreaza-Kaufman D, Venkateswaran N, et al. Update on pharmacotherapy for ocular surface squamous neoplasia. *Eye and Vis* 2019;6:24. <https://doi.org/10.1186/s40662-019-0150-5>

**Lymphoma**

**High-Dose Methotrexate, Rituximab and Temozolomide for Primary and Secondary CNS Lymphoma (LYHDMRTEM)** — The BC Cancer Lymphoma and Myeloma Tumour Group is implementing a newly revised high-dose methotrexate (HD MTX)-containing treatment program. Eligibility for LYHDMRTEM includes newly diagnosed or recurrent primary and secondary CNS lymphoma. LYHDMRTEM is comprised of HD MTX, rituximab and temozolomide; temozolomide is administered daily for 5 days on alternate cycles and is typically initiated at cycle 2.<sup>7</sup> Moving forward, all patients previously eligible for LYHDMRP, LYHDMTXP or LYHDMTXR will be eligible for treatment with LYHDMRTEM. The protocols LYHDMRP, LYHDMTXP and LYHDMTXR will be deleted and/or will no longer be available. Please see the table below for further clarification.

	Protocol Code	CNS Lymphoma Indications	Agents	Status
<b>Newly Revised Protocol</b>	<b>LYHDMRTEM</b>	Primary or secondary Newly diagnosed or recurrent	HD MTX Rituximab Temozolomide	<i>Newly revised from LYHDMRP</i>
<b>Previous Protocols</b>	<b>LYHDMRP</b>	Primary	HD MTX Rituximab	<i>Revised and renamed as LYHDMRTEM</i>
	<b>LYHDMTXP</b>	Primary	HD MTX	<i>Deleted; replaced by LYHDMRTEM</i>
	<b>LYHDMTXR</b>	Secondary or recurrent	HD MTX	<i>Deleted; replaced by LYHDMRTEM</i>

**Reference**

- Rubenstein JL, Hsi ED, Johnson JL, et al. Intensive chemotherapy and immunotherapy in patients with newly diagnosed primary CNS lymphoma: CALGB 50202 (Alliance 50202). *J Clin Oncol* 2013;31(25):3061-3068. <https://doi.org/10.1200/JCO.2012.46.9957>

All BC Cancer Drug Manual<sup>®</sup> documents are available in the [Cancer Drug Manual<sup>®</sup>](#) on the BC Cancer website.

### New Documents

Note that the following drug is not a BC Cancer Benefit Drug and requires application to the BC Cancer Compassionate Access Program (CAP). The corresponding Interim Monograph is made available for reference only.

The **Amivantamab Interim Monograph** has been developed. **Amivantamab** is a low-fucose human IgG1 antibody that binds to EGFR and MET. It is used in the treatment of non-small cell lung cancer. Dosing is based on the patient's baseline body weight. In cycle 1, amivantamab is administered weekly for 4 weeks, with week 1 following a split dose regimen on days 1 and 2. From cycle 2 onwards, amivantamab is administered every two weeks.

Highlights from this document include:

- premedication with antihistamine and antipyretic is recommended prior to all infusions; premedication with a glucocorticoid is required for cycle 1, week 1
- dosing regimen and infusion rate are assigned according to baseline weight; it is important to follow the correct dosing regimen (*under 80 kg, and 80 kg and over*)
- skin reactions are very common, although severe reactions are rare; sun exposure should be limited during treatment and for two months after treatment has ended

**Amivantamab** 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:

#### **Fluorouracil Monograph**

*Side Effects:* added new paragraph for toxicity secondary to ocular administration

*Solution Preparation and Compatibility:* added instructions for preparation of eye drops

*Parenteral Administration:* added ocular administration as new route of administration

*Dosage Guidelines:* added dosing information for ocular administration

#### **Gilteritinib Monograph**

*Dosage Guidelines:* updated with new protocol

#### **Leucovorin Monograph and Chemotherapy Preparation and Stability Chart**

*Supply and Storage:* updated to include GMP brand

**Chemotherapy Preparation and Stability Chart:** added all available vial sizes; updated vial stability for new vial sizes

## Benefit Drug List

### New Programs

The following new treatment programs have been added to the BC Cancer [Benefit Drug List](#) effective 01 September 2021:

Protocol Title	Protocol Code	Benefit Status
Therapy for Metastatic Castration-Sensitive Prostate Cancer using <b>Abiraterone</b> and <b>Prednisone</b>	<b>UGUMCSPABI</b>	Restricted
Therapy of Relapsed or Refractory FLT3+ Acute Myeloid Leukemia using <b>Gilteritinib</b>	<b>ULKAMLGIL</b>	Restricted
Topical Therapy for Ocular Malignancies using <b>Fluorouracil Eye Drops</b>	<b>OCFU</b>	Class I

### Revised Programs

The following treatment programs have been revised on the BC Cancer [Benefit Drug List](#) effective 01 September 2021:

Protocol Title	Protocol Code	Benefit Status
Treatment of Acute Myeloid Leukemia using <b>Gemtuzumab Ozogamicin</b> with Induction and Consolidation Chemotherapy	<b>LKGEMOZ</b>	Class I <i>(Previously Restricted)</i>
Treatment of Primary and Secondary CNS Lymphoma with <b>High-Dose Methotrexate, Rituximab</b> and <b>Temozolomide</b>	<b>LYHDMRTEM</b>	Class I <i>(LYHDMRP revised to LYHDMRTEM; LYHDMTXP and LYHDMTXR replaced by LYHDMRTEM)</i>

### Deleted Programs

The following treatment programs have been deleted from the BC Cancer [Benefit Drug List](#) effective 01 September 2021:

Protocol Title	Protocol Code	Benefit Status
Treatment of Primary Intracerebral Lymphoma with <b>High-Dose Methotrexate</b>	<b>LYHDMTXP</b>	Deleted <i>(Replaced by LYHDMRTEM)</i>
Treatment of Secondary CNS Lymphoma or Recurrent Intracerebral Lymphoma with <b>High-Dose Methotrexate</b>	<b>LYHDMTXR</b>	Deleted <i>(Replaced by LYHDMRTEM)</i>

## 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
UGUMCSPABI	Therapy for Metastatic Castration-Sensitive Prostate Cancer using Abiraterone and Prednisone	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
ULKAMLGIL	Therapy of Relapsed or Refractory FLT3+ Acute Myeloid Leukemia using Gilteritinib	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
OCFU	Topical Therapy for Ocular Malignancies using Fluorouracil Eye Drops	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

Protocol Code	Protocol Title	Protocol	PPPO	Handout
<b>BR   Breast</b>				
BRAJPAM	Adjuvant Therapy for Breast Cancer in Postmenopausal Women using Pamidronate	<i>Treatment interval clarified</i>	<i>Treatment interval clarified</i>	----
BRAJZOL2	Adjuvant Therapy for Breast Cancer in Postmenopausal Women using 3-Monthly Zoledronic Acid	<i>Treatment interval clarified</i>	<i>Treatment interval clarified</i>	----
BRAJZOL5	Adjuvant Therapy for Breast Cancer in Postmenopausal Women using 6-Monthly Zoledronic Acid	<i>Treatment interval clarified</i>	<i>Treatment interval clarified</i>	----
BRAVPAM	Prevention of Skeletal-Related Events Secondary to Breast Cancer Metastases using Pamidronate	<i>Tests and treatment interval clarified</i>	<i>Tests and treatment interval clarified</i>	----
BRAVZOL	Treatment of Acute Bone Pain Secondary to Breast Cancer Metastases using IV Zoledronic Acid	<i>Institution name updated and Eligibility clarified</i>	<i>Treatment interval clarified</i>	----
<b>GI   Gastrointestinal</b>				
GIAVFL	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer using Fluorouracil Injection and Infusion and Leucovorin Infusion	<i>Tests and Monitoring updated</i>	<i>Return Appointment Orders updated</i>	----
GIAVPG	First-Line Palliative Chemotherapy for Advanced Gallbladder Cancer and Cholangiocarcinoma using Gemcitabine and Cisplatin	<i>Institution name and Eligibility updated</i>	----	<i>Cancer types updated</i>

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

Protocol Code	Protocol Title	Protocol	PPPO	Handout
<b>GIFFIRB</b>	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer using Irinotecan, Fluorouracil, Leucovorin and Bevacizumab	<i>Tests and Monitoring updated</i>	<i>Return Appointment Orders updated</i>	----
<b>GIOLFIRI</b>	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer using Irinotecan, Fluorouracil and Leucovorin	<i>Tests and Monitoring updated</i>	<i>Return Appointment Orders updated</i>	----
<b>GIPAVFFIRI</b>	Second-Line Treatment for Metastatic Pancreatic Cancer using Irinotecan, Fluorouracil and Leucovorin	<i>Tests and Monitoring updated</i>	<i>Return Appointment Orders updated</i>	----
<b>UGIPRRT</b>	Peptide Receptor Radionuclide Therapy (PRRT) using <sup>177</sup> Lu-Dotatate (LUTATHERA) for Treatment in Patients with Somatostatin Receptor Positive Midgut Neuroendocrine Tumours	<i>Tests clarified</i>	<i>Tests clarified</i>	----
<b>GIRAJCOX</b>	Adjuvant or Neoadjuvant Combination Chemotherapy for Stage III Rectal Cancer using Oxaliplatin and Capecitabine	<i>Treatment and References updated</i>	----	<i>Treatment Summary updated</i>
<b>GIRAJFFOX</b>	Adjuvant or Neoadjuvant Combination Chemotherapy for Stage III Rectal Cancer using Oxaliplatin, Fluorouracil and Leucovorin	<i>Treatment and References updated</i>	----	<i>Treatment Summary updated</i>
<b>GU   Genitourinary</b>				
<b>GUBPWRT</b>	Treatment of Locally Advanced Bladder Cancer with Weekly Cisplatin and Concurrent Radiation	----	<i>Lab requirements updated</i>	----
<b>HN   Head and Neck</b>				
<b>UHNAVPMBF</b>	First-Line Treatment of Advanced Squamous Cell Carcinoma of the Head and Neck with Pembrolizumab	<i>Eligibility updated</i>	----	----
<b>LK   Leukemia</b>				
<b>ULKGEMOZ</b>	Treatment of Acute Myeloid Leukemia using Gemtuzumab Ozogamicin with Induction and Consolidation Chemotherapy	<i>Protocol Code (U removed) and Eligibility revised</i>	----	----
<b>LY   Lymphoma</b>				
<b>LYABVD</b>	Treatment of Hodgkin Lymphoma with Doxorubicin, Bleomycin, Vinblastine and Dacarbazine	<i>Bag size clarified</i>	<i>Bag size clarified</i>	----
<b>LYHDMRPTM</b>	Treatment of Primary <b>and Secondary CNS</b> <del>Intracerebral</del> Lymphoma with High-Dose Methotrexate, <del>and</del> Rituximab <b>and Temozolomide</b>	<i>Protocol title, Protocol Code, Eligibility, Premedications, Treatment, Dose Modifications and References revised</i>	<b>Inpatient PPPO revised</b>	----
<b>LYRITUX</b>	Treatment of Lymphoma with Single-Agent Rituximab	<i>Eligibility clarified</i>	----	----

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

Protocol Code	Protocol Title	Protocol	PPPO	Handout
<b>MO   Miscellaneous Origin</b>				
<b>MOIT</b>	Solid Tumours using Intrathecal Methotrexate and/or Thiotepa and/or Cytarabine	<i>Contact Physician updated</i>	----	----
<b>MY   Myeloma</b>				
<b>MYBORPRE</b>	Treatment of Multiple Myeloma using Bortezomib, Dexamethasone with or without Cyclophosphamide as Induction Pre-Stem Cell Transplant	<i>Formatting fixed</i>	----	----
<b>MYPAM</b>	Treatment of Multiple Myeloma with Pamidronate	<i>Tests and treatment interval clarified</i>	<i>Tests and treatment interval clarified</i>	----
<b>MYZOL</b>	Treatment of Multiple Myeloma with Zoledronic Acid	<i>Treatment interval clarified</i>	<i>Treatment interval clarified</i>	
<b>SA   Sarcoma</b>				
<b>SAAVGR</b>	Third-Line Therapy of Advanced Gastrointestinal Stromal Cell Tumours (GIST) using Regorafenib	<i>Dispensing procedures deleted</i>	<i>Dispensing procedures deleted</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
Manufacturer Patient Assistance Programs: <a href="http://www.bccancer.bc.ca/mpap">http://www.bccancer.bc.ca/mpap</a>		
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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