Systemic Therapy Update



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For Health Professionals Who Care For Cancer Patients

Inside This Issue:

- Editor's Choice New Programs: 3-Monthly Zoledronic Acid in Post-Menopausal Women with Early Breast Cancer (BRAJZOL2), Panitumumab with FOLFIRI for Metastatic Colorectal Cancer (UGIFFIRPAN), Obinutuzumab with Bendamustine for Rituximab-Refractory Follicular Lymphoma (ULYOBBEND), Zoledronic Acid for Multiple Myeloma (MYZOL)
- Provincial Systemic Therapy Program Policies Parenteral Drug Therapy Policy Updated
- Patients Corner Updated Systemic Therapy Patient Group-Teach Presentation
- Continuing Professional Development BC Cancer Summit (Registration Now Open)
- Benefit Drug List New: BRAJZOL2, UGIFFIRPAN, ULYOBBEND, MYZOL; Correction: GIENDO2

- Cancer Drug Manual New: Alectinib; Revised: Azacitidine, Clodronate, Everolimus, Mitomycin
- List of New and Revised Protocols, Provincial Pre-Printed Orders and Patient Handouts New: BRAJZOL2, GIENDO2, UGIFFIRPAN, ULYOBBEND, MYZOL; Revised: BRAJZOL5, UBRAVPALAI, CNAJ12TZRT, CNAJTZRT, CNBEV, CNELTZRT, GICIRB, GICOXB, GIFFIRB, GIFFOXB, UGIGAVRAMT, GOCXCATB, UGOOVBEVG, UGOOVBEVLD, UGOOVBEVP, UGOOVBEVV, GOSADG, GOTDEMACO, GOTDLR, GUNAJPG, ULKAMLAS, ULKMDSA, LUAJNP, LUAJPC, LUAVAFAT, ULUAVCRIZF, LUAVERL, LUAVGEFF, LUAVMTNE, LUAVPC, LUAVPP, ULYROMI, MYPAM, USMAVVIS
- Website Resources and Contact Information

EDITOR'S CHOICE

New Programs

Effective 01 July 2018, the BC Cancer Provincial Systemic Therapy Program has approved the following programs.

Breast:

3-Monthly Zoledronic Acid for Post-Menopausal Women with Early Breast Cancer (BRAJZOL2) – The BC Cancer Breast Tumour Group is offering this new treatment regimen as an alternative to the existing BRAJZOL5 regimen (previously named BRAJZOL) in post-menopausal women with breast cancer. Only patients with select stages of early breast cancer (as specified on the treatment protocol) are eligible.

BRAJZOL2	Zoledronic acid 4 mg IV every 3 months x 2 years (Total 8 doses)
BRAJZOL5	Zoledronic acid 4 mg IV every 6 months x up to 5 years (Total 10 doses)

A phase III randomized controlled trial (SUCCESS A) showed no difference in disease-free survival, overall survival, or bone recurrences as first distant recurrence between 2 vs. 5 years of zoledronic acid. Patients

EDITOR'S CHOICE

currently on the 5-year regimen (BRAJZOL5) may be switched to the 2-year regimen (BRAJZOL2). All new eligible patients are encouraged to start on the 2-year regimen (BRAJZOL2).

Gastrointestinal:

Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Irinotecan, Fluorouracil, Leucovorin, and Panitumumab (UGIFFIRPAN) — The BC Cancer Gastrointestinal Tumour Group has implemented this treatment regimen as a first-line treatment option in patients with metastatic colorectal cancer who are not suitable for bevacizumab therapy. In a phase III randomized controlled trial, panitumumab with FOLFIRI resulted in an improved progression-free survival (PFS) compared to FOLFIRI alone (median PFS 5.9 mo vs. 3.9 mo, HR 0.73, p=0.04), while demonstrating no overall survival (OS) benefit.² Patients who have Gilbert's Syndrome or who are at greater risk for irinotecan toxicities should be considered for panitumumab in combination with FOLFOX (UGIFFOXPAN).

Lymphoma:

Obinutuzumab in Combination with Bendamustine for Rituximab-Refractory Follicular Lymphoma (ULYOBBEND) – The BC Cancer Lymphoma Tumour Group is implementing this new treatment combination for patients who did not respond to or relapsed within 6 months of prior rituximab-containing therapy. In a phase III randomized controlled trial (GANDOLIN) involving patients with rituximab-refractory indolent non-Hodgkin lymphoma, combination therapy demonstrated improved PFS compared to bendamustine alone (median PFS 25.8 mo vs. 14.1 mo, HR 0.57, p<0.0001). In addition, with longer follow-up, OS was also improved (median OS not yet reached, HR 0.67, p=0.027). Overall, combination therapy was well tolerated.

Multiple Myleoma:

Zoledronic Acid for Multiple Myeloma (MYZOL) – The BC Cancer Lymphoma/Myeloma Tumour Group is offering zoledronic acid as a treatment alternative to pamidronate (MYPAM) for multiple myeloma. Zoledronic acid is the only bisphosphonate shown to improve overall survival compared to clodonate, but is associated with higher rates of osteonecrosis of the jaw (4% vs. 1%). At BC Cancer, zoledronic acid is preferred over pamidronate given the overall survival data, except in the setting of renal failure. The eligibility criteria in the MYPAM protocol has been updated to reflect this preference. Of note, there is no head-to-head survival comparison between zoledronic acid and pamidronate.

References

- 1. Janni W, Friedl TWP, Fehm T, et al. Extended adjuvant bisphosphonate treatment over five years in early breast cancer does not improve disease-free and overall survival compared to two years of treatment: Phase III data from the SUCCESS A study [abstract]. In: Proceedings of the San Antonio Breast Cancer Symposium; 2017 Dec 5-9. San Antonio, Texas. Abstract GS1-06.
- 2. Peeters M, Price TJ, Cervantes A, et al. Randomized phase III study of panitumumab with fluorouracil, leucovorin, and irinotecan (FOLFIRI) vs FOLFIRI alone as second-line treatment in patients with metastatic colorectal cancer. J Clin Oncol 2010;28:4706-4713.
- 3. Sehn LH, Chua N, Mayer J, et al. Obinutuzumab plus bendamustine versus bendamustine monotherapy in patients with rituximab-refractory indolent non-Hodgkin lymphoma (GADOLIN): a randomised, controlled, open-label, multicentre, phase 3 trial. Lancet Oncol 2016;17:1081-
- 4. Cheson BD, Chua N, Mayer J, et al. Overall survival benefit in patients with rituximab-refractory indolent non-Hodgkin lymphoma who received obinutuzumab plus bendamustine induction and obinutuzumab maintenance in the GADOLIN study. J Clin Oncol . Advance online publication. doi.10.1200/JCO.2017.76.3656
- 5. Morgan GJ, Davies FE, Gregory WM, et al. First-line treatment with zoledronic acid as compared with clodronic acid in multiple myeloma (MRC Myeloma IX): a randomised controlled trial. Lancet 2010;376:1989-1999.

PROVINCIAL SYSTEMIC THERAPY PROGRAM POLICIES

PARENTERAL DRUG THERAPY POLICY UPDATED

The *Provincial Systemic Therapy Program Policy III-90* – *Parenteral Drug Therapy Policy* has been updated to remove the requirement for creating a Parenteral Drug Therapy Monograph (PDTM) for clinical trials drugs. Clinicians are directed to consult documents prepared by the Clinical Trials Unit for drug and administration information. Pharmacists may also consult any investigational drug summaries developed by the clinical trials pharmacist.

PATIENTS CORNER

UPDATED SYSTEMIC THERAPY PATIENT GROUP-TEACH PRESENTATION

Effective 03 July 2018, an updated version of the presentation, "Introduction to Systemic Therapy: A Presentation for Patients and Families", will be available on the BC Cancer <u>website</u>. This presentation is used during the introductory chemotherapy group-teach sessions (commonly known as "chemo teach") for new patients and family members. The Provincial Systemic Therapy Group Teach Working Group reviewed and revised this presentation in consultation with programs and leaders across BC Cancer.

What has Changed?

Highlights of changes include:

- 1. The term "systemic therapy" has replaced "chemotherapy" to more accurately reflect the different therapies patients may receive (e.g. chemotherapy, immunotherapy, hormone therapy, targeted therapy).
- 2. The word "drug" has replaced "medication" to simplify the language and to keep the reading level around the eighth-grade.
- 3. BC Cancer logo and colour scheme have been updated to the new branding standards.
- 4. A new slide on *Blood Clots* has been added to the Risks and Potential Side Effects section.
- 5. A slide on Speech-Language Pathology has been added.

Where Can I Find the Presentation?

Presentation slides:

- http://www.bccancer.bc.ca/health-professionals/education-development/nursing/chemotherapypatient-education#Materials
- H:\EVERYONE\nursing\EDUCATION\Chemotherapy Patient Education (BC Cancer internal drive) Video of the presentation slides with voice-over:
- http://www.bccancer.bc.ca/health-info/coping-with-cancer/video-resources (under "Chemotherapy Teaching Session")

Contact:

Questions about the new presentation slides can be directed to Devon Poznanski, Provincial Lead, Patient Education (email: dpoznanski@bccancer.bc.ca; tel: 604-877-6000 ext. 676123).

CONTINUING PROFESSIONAL DEVELOPMENT

BC Cancer Summit – Registration Now Open

It is with great excitement that BC Cancer announces the inaugural BC Cancer Summit scheduled for November 23-24, 2018 in Vancouver, BC. The theme for the conference is #80yearsofcare and its programme encompasses topics that span a wide spectrum of oncology specialties and disciplines. Registration is open to anyone with an interest in cancer care, whether your role is within BC Cancer, the Communities Oncology Network, the community or other settings. The BC Cancer Summit also welcomes colleagues across the country so please spread the word to your colleagues in other jurisdictions and your professional associations.

Date: November 23-24, 2018

Location: Sheraton Wall Centre, Vancouver, BC

Registration Opens: July 1, 2018

Early Bird Deadline: September 28, 2018
Website: www.bccancersummit.ca

Please see the conference website for further information about the programme, topics, speakers, and registration information.

BENEFIT DRUG LIST

New Programs

Effective 01 July 2018, the following treatment programs have been added to the BC Cancer <u>Benefit Drug</u> <u>List</u>:

Protocol Title	Protocol Code	Benefit Status
Adjuvant Treatment of Post-Menopausal Women using 3-Monthly Zoledronic Acid	BRAJZOL2	Class I
Palliative Combination Chemotherapy for Metastatic Colorectal Cancer using Irinotecan, Fluorouracil, Leucovorin, and Panitumumab	UGIFFIRPAN	Restricted
Treatment of Rituximab-Refractory Follicular Lymphoma with Obinutuzumab in Combination with Bendamustine	ULYOBBEND	Restricted
Treatment of Multiple Myeloma with Zoledronic Acid	MYZOL	Class I

BENEFIT DRUG LIST

CORRECTION

In the June issue of the Systemic Therapy Update, the following treatment program was incorrectly deleted from the BC Cancer <u>Benefit Drug List</u>. Effective 01 July 2018, this program will be reinstated on the Benefit Drug List, and the associated protocol and pre-printed order re-posted on the BC Cancer website.

Protocol Title	Protocol Code
Palliative Therapy for Pancreatic Endocrine Tumours using Streptozocin and Doxorubicin	GIENDO2

CANCER DRUG MANUAL

NEW MONOGRAPHS AND PATIENT HANDOUTS

The following drug is <u>NOT</u> a BC Cancer Benefit Drug, and requires application to the BC Cancer Compassionate Access Program. Its corresponding Interim Monograph and Patient Handout are made available for reference only.

The **Alectinib Monograph** and **Patient Handout** have been developed with expert review provided by Dr. Christopher Lee (medical oncologist) and Alysha Bharmal (pharmacist) of the BC Cancer Lung Tumour Group. Alectinib is a potent tyrosine kinase receptor inhibitor selective for anaplastic lymphoma kinase (ALK). Alectinib inhibits tumour cell proliferation and induces tumour cell death by inhibiting ALK phosphorylation and ALK-mediated downstream signaling pathways. Alectinib is used in the treatment of ALK-positive non-small cell lung cancer. The usual dosage is 600 mg orally twice daily with food (food increases alectinib bioavailability). Please note that alectinib capsules contain lactose so caution should be exercised in patients with lactose intolerance.

Highlights of these documents include:

- Commonly reported side effects include anemia, bradycardia, constipation, edema, fatigue, lymphopenia, myalgia and weakness
- Vision changes and photosensitivity have been reported in 10% of patients
- Rare, but serious, side effects include gastrointestinal perforation, hepatotoxicity and interstitial lung disease/pneumonitis.

CANCER DRUG MANUAL

REVISED MONOGRAPHS AND PATIENT HANDOUTS

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

Azacitidine Monograph:

 Parenteral Administration table – updated subcutaneous administration section to indicate that volumes over 4 mL* should be injected into 2 separate sites

*For further information about the 4 mL maximum subcutaneous injection volume, see the <u>June 2018</u> <u>issue</u> of the Systemic Therapy Update.

Clodronate Monograph, Patient Handout (IV) and Chemo Chart:

- All information related to the IV formulation has been removed from these documents as the IV formulation has been discontinued in Canada*
- Patient Handout (IV) removed from the BC Cancer website
 *For further information about the discontinuation of IV clodronate, see the <u>June 2018 issue</u> of the Systemic Therapy Update.

Everolimus Monograph:

- Uses updated to include all approved tumour indications
- Cautions added statement that the DISPERZ® formulation (tablets for oral suspension) is not interchangeable with the original everolimus tablet formulation
- Supply and Storage added new tablet strengths

Mitomycin:

Chemo Chart – updated to include Accord brand

LIST OF REVISED PROTOCOLS, PRE-PRINTED ORDERS 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. Protocol codes for treatment requiring BC Cancer 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						
BRAJZOL2	$\overline{\square}$	V		Adjuvant Treatment of Post-Menopausal Women using 3-Monthly Zoledronic Acid		
GIENDO2	$\overline{\checkmark}$	V		Palliative Therapy for Pancreatic Endocrine Tumours using Streptozocin and Doxorubicin		

NEW PROTOCOLS, PPPOS AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED)						
CODE	Protocol	PPPO	Patient Handout	Protocol Title		
UGIFFIRPAN	$\overline{\checkmark}$	V	V	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer using Irinotecan, Fluorouracil, Leucovorin, and Panitumumab		
ULYOBBEND	\square	V		Treatment of Rituximab-Refractory Follicular Lymphoma (FL) with Obinutuzumab in Combination with Bendamustine		
MYZOL	$\overline{\checkmark}$	V		Treatment of Multiple Myeloma with Zoledronic Acid		

REVISED PROTOCOLS, PPPOS AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED)							
CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title		
BRAJZOL5		$\overline{\square}$		Protocol code revised	Adjuvant Treatment of Post-Menopausal Women using 6-Monthly Zoledronic Acid		
UBRAVPALAI	V			Minor typo corrected	Therapy of Advanced Breast Cancer using Palbociclib with Aromatase Inhibitor		
CNAJ12TZRT	V			Eligibility, antibiotics and dose adjustment clarified	Concomitant (Dual Modality) and 12 Cycles of Adjuvant Temozolomide for Newly Diagnosed Astrocytomas and Oligodendrogliomas with Radiation		
CNAJTZRT	Ø			Eligibility, antibiotics and dose adjustment clarified	Concomitant (Dual Modality) and Adjuvant Temozolomide for Newly Diagnosed Malignant Gliomas with Radiation		
CNBEV	V	Ø		Diluent volume for flushing line, institutional name and logo updated	Palliative Therapy for Recurrent Malignant Gliomas using Bevacizumab With or Without Concurrent Etoposide or Lomustine		
CNELTZRT	Ø			Eligibility, antibiotics and dose adjustment clarified	Treatment of Elderly Newly Diagnosed Glioma Patient with Concurrent and Adjuvant Temozolomide and Radiation Therapy		
GICIRB	V	Ø		Diluent volume for flushing line, tests, institutional name and logo updated	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer using Irinotecan, Bevacizumab and Capecitabine		
GICOXB	V	Ø		Diluent volume for flushing line, institutional name and logo updated	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer using Oxaliplatin, Bevacizumab and Capecitabine		
GIFFIRB		Ø		Diluent volume for flushing line, institutional name and logo updated	Metastatic Colorectal Cancer using Irinotecan, Fluorouracil Leucovorin and Bevacizumah		

REVISED PROTOCOLS, PPPOS AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED)							
CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title		
GIFFOXB		V		Diluent volume for flushing line updated	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer using Oxaliplatin, Fluorouracil, Leucovorin, and Bevacizumab		
UGIGAVRAMT	\square			Treatment sequence specified, paclitaxel diluent volume clarified	Second-Line Therapy for Metastatic or Locally Advanced Gastric or Gastroesophageal Junction Cancer using Weekly Paclitaxel and Ramucirumab		
GOCISP	V			Minor typo corrected	Alternative Treatment of Gynecological Malignancies using Cisplatin and Paclitaxel		
GOCXCATB		Ø		Diluent volume for flushing line, institutional name and logo updated	Treatment of Metastatic or Recurrent Cancer of the Cervix with Bevacizumab, Carboplatin and Paclitaxel		
UGOOVBEVG	Ø	Ø		Exclusions, tests and diluent volume for flushing line updated	Treatment of Platinum-Resistant Epithelial Ovarian Cancer with Bevacizumab and Gemcitabine		
UGOOVBEVLD	Ø	Ø		Exclusions, tests and diluent volume for flushing line updated	Platinum-Resistant Epithelial Ovarian Cancer with Bevacizumab and Doxorubicin Pegylated Liposomal (CAELYX®)		
UGOOVBEVP	V	V		Exclusions, tests and diluent volume for flushing line updated	Treatment of Platinum-Resistant Epithelial Ovarian Cancer with Bevacizumab and Paclitaxel		
UGOOVBEVV	V	V		Exclusions, tests and diluent volume for flushing line updated	Treatment of Platinum-Resistant Epithelial Ovarian Cancer with Bevacizumab and Vinorelbine		
GOSADG		$\overline{\checkmark}$		Dose modification clarified	Treatment of Uterine Sarcoma Cancer using Docetaxel and Gemcitabine		
GOTDEMACO				Eligibility, exclusions and treatment clarified	Therapy for High-Risk Gestational Trophoblastic Neoplasia (GTN) using Etoposide, Methotrexate, Leucovorin (Folinic Acid), Dactinomycin, Cyclophosphamide and Vincristine		
GOTDLR	V			Eligibility, exclusions and treatment clarified	Therapy for Low-Risk Gestational Trophoblastic Cancer using Dactinomycin and Methotrexate		
GUNAJPG			V	Typo corrected	Neoadjuvant Therapy for Urothelial Carcinoma using Cisplatin and Gemcitabine		
ULKAMLAS		$\overline{\checkmark}$		Maximum injection volume updated	Therapy of Acute Myeloid Leukemia using Azacitidine and Sorafenib		

REVISED PROTOCOLS, PPPOS AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED)							
CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title		
ULKMDSA	Ø	Ø		Eligibility and maximum injection volume updated	Therapy of Myelodysplastic Syndrome using Azacitidine		
LUAJNP	V	V	\square	Tests clarified, institutional name and logo updated	Adjuvant Cisplatin and Vinorelbine Following Resection of Non-Small Cell Lung Cancer		
LUAJPC	V	V	\square	Tests clarified, institutional name and logo updated	Adjuvant Carboplatin and Paclitaxel Following Resection of Stage I, II and IIIA Non-small Cell Lung Cancer		
LUAVAFAT	\square	V	\square	Tests clarified, institutional name and logo updated	First-Line Treatment of Epidermal Growth Factor Receptor (EGFR) Mutation-Positive Advanced Non-Small Cell Lung Cancer (NSCLC) with Afatinib		
ULUAVCRIZF	V	V	\square	Tests clarified, institutional name and logo updated	First-Line Treatment of ALK-Positive Advanced Non-Small Cell Lung Cancer (NSCLC) with Crizotinib		
LUAVERL	V	V	V	Tests clarified, institutional name and logo updated	Second- or Later-Line Treatment of Advanced Non-Small Cell Lung Cancer (NSCLC) with Erlotinib		
LUAVGEFF	Ø		\square	Tests clarified, institutional name and logo updated	First-Line Treatment of Epidermal Growth Factor Receptor (EGFR) Mutation-Positive Advanced Non-Small Cell Lung Cancer (NSCLC) with Gefitinib		
LUAVMTNE	Ø	Ø	Ø	Tests clarified, institutional name and logo updated	Maintenance Therapy of Advanced Non-Small Cell Lung Cancer (NSCLC) with Erlotinib after First-Line Chemotherapy		
LUAVPC	Ø	Ø	Ø	Tests clarified, institutional name and logo updated	First-Line Treatment of Advanced Non-Small Cell Lung Cancer (NSCLC) with Carboplatin and Paclitaxel		
LUAVPP	V	Ø	Ø	Tests clarified, institutional name and logo updated	First-Line Treatment of Advanced Non-Small Cell Lung Cancer with Platinum and Pemetrexed		
ULYROMI		$\overline{\checkmark}$		Timing of lab requirement updated	Treatment of Relapsed or Refractory Peripheral T-Cell Lymphoma (PTCL) with Romidepsin		
МҮРАМ	V			Eligibility clarified	Treatment of Multiple Myeloma with Pamidronate		
USMAVVIS		\square		Requirements for the ERIVEDGE® Pregnancy Prevention Program added	Treatment of Metastatic or Locally Advanced Basal Cell Carcinoma Using Vismodegib		

Website Resources and Contact Information

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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
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BC Cancer-Abbotsford	604-851-4710 Toll Free 877-547-3777		
BC Cancer-Prince George (Centre for the North)	250-645-7300 Toll Free 888-775-7300		
BC Cancer-Surrey	604-930-2098 Toll Free 800-523-2885		
BC Cancer-Kelowna	250-712-3900 Toll Free 888-563-7773		
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