

# Systemic Therapy Update



BC Cancer Agency

CARE + RESEARCH

An agency of the Provincial Health Services Authority

January 2010

Volume 13, Number 1

For health professionals who care for cancer patients  
Available online at [www.bccancer.bc.ca/HPI/ChemotherapyProtocols/stupdate](http://www.bccancer.bc.ca/HPI/ChemotherapyProtocols/stupdate)

## INSIDE THIS ISSUE

- [Editor's Choice: Highlights of Changes in Protocols, Pre-Printed Orders and Patient Handouts](#) – Sarcoma, Breast Cancer
- [Drug Update](#) – Chemotherapy and Pregnancy, Decreased Potency of Heparin, Azacitidine (VIDAZA®) Injection, Foreign Particles in Thyrotropin Alfa Injectable
- [Benefit Drug List](#) – Gemcitabine, Nab-Paclitaxel
- [List of New and Revised Protocols, Pre-Printed Orders and Patient Handouts](#) – **New:** GIENDO2, GIGAVECC, GIGAVECF, UGIGDCF, UMYMPBOR, USAAVGEMD, SAVDCM **Revised:** BRAJTR, BRAVGEMD, BRAVABR, CNTEMOZ, UCNTEMOZMD, UGIAVTZCAP, GOSADG, GUBEP, UGUSORAF, LUAJNP, LUAVPEM, UMYBORTEZ, UMYLENDEX, PUCAT, USAAVGS, SAIME, SAVAC, SAVACM
- [Website Resources and Contact Information](#)

## EDITOR'S CHOICE:

### HIGHLIGHTS OF CHANGES IN PROTOCOLS, PRE-PRINTED ORDERS AND PATIENT HANDOUTS

The **Sarcoma Tumour Group** has introduced two new protocols for soft tissue sarcoma:

- Combination of gemcitabine and docetaxel as a second or third line therapy for soft tissue sarcomas (USAAVGEMD).
- Combination of vincristine, dactinomycin, cyclophosphamide and mesna as adjuvant therapy for rhabdomyosarcoma (SAVDCM)

The **Breast Tumour Group** has introduced the use of nanoparticle, albumin-bound (nab)-paclitaxel (ABRAXANE®) as palliative therapy for metastatic breast Cancer (BRAVABR).

## DRUG UPDATE

**Chemotherapy and Pregnancy** The Provincial Drug Information and the Breast Tumour Group have developed a [table](#) of chemotherapy drugs that may be used in pregnant women with breast cancer. The table is posted on the website in two locations:

- Cancer Drug Manual:
  - [www.bccancer.bc.ca/HPI/DrugDatabase/Appendices/7.+Special+Populations](http://www.bccancer.bc.ca/HPI/DrugDatabase/Appendices/7.+Special+Populations)
- Cancer Management Guidelines:
  - [www.bccancer.bc.ca/HPI/CancerManagementGuidelines/Breast/Management/BreastCancerinPregnancy](http://www.bccancer.bc.ca/HPI/CancerManagementGuidelines/Breast/Management/BreastCancerinPregnancy)

Chemotherapy in a pregnant woman can pose life-threatening complications for a developing fetus. Use of chemotherapy should be avoided during the first trimester because it increases the risk of spontaneous abortion, fetal death, and major malformations. However, chemotherapy can be considered in later stages

of pregnancy if termination is not desired or if chemotherapy cannot be delayed until after the baby's delivery. The decision to use chemotherapy during pregnancy must be weighed against the effect of treatment delay on maternal survival.

Drugs should be avoided in pregnancy if they are high lipid soluble or diffusible, or if they have low molecular weight because these characteristics favour transfer of drugs from mother to fetus. Safe use of some chemotherapy drugs, especially during the second and third trimester, has been reported. Case reports on the use of anthracyclines, vinca alkaloids and certain single and multi-agent treatments suggest short-term clinical safety.

Submitted by:

Victoria Kletas BSc Pharm, MSc  
Clinical Pharmacist  
Vancouver Centre – BC Cancer Agency

**Azacitidine (VIDAZA®) Injection** will be commercially available on 4 January, 2010. The recommended dose is 75 mg/m<sup>2</sup> given subcutaneously for 7 consecutive days, repeated every 28 days. This regimen has been shown to prolong overall survival by about 9 months compared to supportive care in patients with higher-risk myelodysplastic syndrome (MDS). Early results of one phase II randomised trial showed similar response rate with alternative dosing regimens that do not require 7 consecutive days dosing. However, to date, there has been no survival data reported associated with these alternative regimens. Therefore, it is important that treatments are planned with consideration of the need for 7-day chemotherapy service.

The BC Cancer Agency Provincial Systemic Therapy Program is not currently funding azacitidine. Compassionate Access Program (CAP) approvals are being given on the condition that there is no cost to the BCCA for the drug. For patients who have been accessing azacitidine via Health Canada's Special Access Program (SAP) and for new patients needing azacitidine for certain types of myelodysplastic syndrome or acute myeloid leukemia (see December 2009 issue of Systemic Therapy Update), enrollment with the Vidaza Access Program (VAP) will be required. This program will:

- source co-pay or deductible support if patients have private insurance
- provide free supply of azacitidine if patients do not have private insurance.

VAP will be available for enrollment until 31 March 2010. For more information, please contact VAP at 1-877-384-292 or [Vidaza@assistprogram.com](mailto:Vidaza@assistprogram.com).

**Decreased Potency of Heparin Products** The potency of some unfractionated heparin products will be decreased by approximately 10% due to new United States Pharmacopeia (USP) manufacturing and testing requirements. The new USP potency reference standard is calibrated to the WHO International Standard for Unfractionated Heparin, so that potency results of all unfractionated heparin products would be the same regardless of which standard is used. *Low molecular weight heparins* will not be affected by this change.

At this time, dosage recommendations are not expected to change. However, some patients may require closer monitoring of their anticoagulation to ensure adequate heparinization. In circumstances where rapid or aggressive anticoagulation is needed, the difference in potency should be considered when determining the dose of unfractionated heparin to be administered.

The manufacturers impacted by the change in the USP reference standard will be implementing measures to distinguish lots with the new standard from lots with the old standard. Starting December 2009, there will be a transition period over the next 2 years where unfractionated heparin products of both the old and new potency will be on the market simultaneously.

For more details, see the Health Canada website [www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/2009/2009\\_191-eng.php](http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/2009/2009_191-eng.php).

**Foreign Particles in Thyrotropin Alfa Injectable (THYROGEN®)** Foreign particles have been found in certain products from Genzyme, including thyrotropin alfa. Genzyme has also received customer reports of foreign particles in some vials of these products. As recommended in the current product monograph, healthcare professionals should visually inspect the lyophilized product prior to reconstitution and the reconstituted product for any foreign particles within each vial and when withdrawn into the syringe.

Foreign particles are a known issue in the manufacture of protein products. The particles observed with the thyrotropin alfa products ranged in size from 140-295 microns and include non-latex rubber originating from the vial stopper, stainless steel particles, and fiber-like material originating from the manufacturing process. Intramuscular injection of foreign particles of this size may cause local reactions at the injection site (e.g., pain, swelling, foreign body granuloma, rash, urticaria). Genzyme has reviewed all adverse events reported to its global safety database (Jan 2004 – Nov 2009) and did not identify any safety concerns that could be potentially related to intramuscular injection of foreign particles.

For more details, see the Health Canada website [http://hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/2009/thyrogen\\_hpc-cps-eng.php](http://hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/2009/thyrogen_hpc-cps-eng.php)

---

## BENEFIT DRUG LIST

---

The following programs have been added on the benefit list effective 1 January 2010:

- **Gemcitabine** (case-by-case) and **Docetaxel** (case-by-case) as a second or third line therapy for soft tissue sarcomas (USAAVGEMD)
- **Nab-Paclitaxel (ABRAXANE®)** (class II) as palliative therapy for metastatic breast cancer (BRAVABR)

**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 and revised protocols, PPPOs and patient handouts for this month are listed below. Protocol codes for treatments requiring “Compassionate Access Program” (previously Undesignated Indication 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
GIENDO2	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Palliative Treatment for Pancreatic Endocrine Tumours using Streptozocin and Doxorubicin
GIGAVECC	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Palliative Therapy for Metastatic or Locally Advanced Stomach or Esophageal Cancer using Epirubicin, Cisplatin and Capecitabine
GIGAVECF	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Palliative Therapy for Metastatic or Locally Advanced Cancer of the Stomach or Esophagus using Epirubicin, Cisplatin and Infusional Fluorouracil
UGIGDCF	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Palliative Treatment of Metastatic or Locally Advanced Stomach, Esophageal-Stomach Junction or Esophageal Cancer using Docetaxel, Cisplatin and Infusional Fluorouracil
UMYMPBOR	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Treatment of Multiple Myeloma using Melphalan, Prednisone and Weekly Bortezomib
USAAVGEMD	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Second or Third Line Therapy for Soft Tissue Sarcomas using Gemcitabine and Docetaxel
SAVDCM	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Adjuvant Therapy for Rhabdomyosarcoma using Vincristine, Dactinomycin, Cyclophosphamide and Mesna

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

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
BRAJTR	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Minor typo corrected</i>	Adjuvant Therapy for Breast Cancer using Trastuzumab (HERCEPTIN®) following the Completion of Chemotherapy (Sequential)
BRAVGEMD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Minor typo corrected</i>	Palliative Therapy for Metastatic Breast Cancer using Gemcitabine and Docetaxel
BRAVABR	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>CAP requirement replaced by class II indication in Eligibility</i>	Palliative Therapy for Metastatic Breast Cancer using Nanoparticle, Albumin-bound (nab)-Paclitaxel
CNTEMOZ	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Timing of dose administration clarified</i>	Therapy for Malignant Brain Tumours using Temozolomide
UCNTEMOZMD	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Timing of dose administration clarified</i>	Therapy for Malignant Brain Tumours Using Metronomic Dosing of Temozolomide

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
UGIAVTZCAP	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Dosing schedule clarified</i>	Palliative therapy of Metastatic Neuroendocrine Cancer using Temozolomide and Capecitabine
GOSADG	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Diluent volume of docetaxel clarified</i>	Treatment of Uterine Sarcoma Cancer Using Docetaxel and Gemcitabine
GUBEP	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Option of prehydration added</i>	Therapy for Intermediate Risk Non-Seminomatous Testicular Cancer using Bleomycin, Etoposide and Cisplatin
UGUSORAF	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Tests clarified</i>	Palliative Therapy for Renal Cell Carcinoma Using Sorafenib (NEXAVAR®)
LUAJNP	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Minor typo corrected, dose modifications for renal dysfunction clarified</i>	Adjuvant Cisplatin and Vinorelbine Following Resection of Non-Small Cell Lung Cancer
LUAVPEM	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Frequency of bloodwork clarified</i>	Second-Line Treatment of Advanced Non-Small Cell Lung Cancer (NSCLC) With Pemetrexed
UMYBORTEZ	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Dexamethasone added to Treatment and Dose modification, Eligibility and Tests sections revised</i>	Treatment of Multiple Myeloma using Bortezomib with Dexamethasone
UMYLENDEX	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Dosing instruction clarified</i>	Therapy of Multiple Myeloma Using Lenalidomide with Dexamethasone
PUCAT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Exclusion criteria clarified</i>	Primary Treatment of Cancer of Unknown Primary Origin Using Carboplatin and Paclitaxel
USAAVGS	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Minor typo corrected</i>	Second Line Treatment of Advanced C-kit Positive Gastrointestinal Stromal Cell Tumours (GIST's) After Imatinib Using Sunitinib
SAIME	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Return appointments section clarified</i>	Etoposide, Ifosfamide-Mesna for Patients with Newly Diagnosed Ewing's Sarcoma/Peripheral Neuroectodermal Tumor (PNET) or Rhabdomyosarcoma or Advanced Soft Tissue or Bony Sarcomas
SAVAC	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Return appointments section clarified</i>	Adjuvant therapy for Newly Diagnosed Ewing's Sarcoma/Peripheral Neuroectodermal Tumor (PNET) or rhabdomyosarcoma using Vincristine, Doxorubicin and Cyclophosphamide
SAVACM	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Mesna dose clarified</i>	Adjuvant Therapy for Newly Diagnosed Ewing's Sarcoma/Peripheral Neuroectodermal Tumor (PNET) or Rhabdomyosarcoma With Pelvic Primaries or Chemotherapy Induced Hematuria Using Vincristine, Doxorubicin, Cyclophosphamide and Mesna

## WEBSITE RESOURCES AND CONTACT INFORMATION

WEBSITE RESOURCES	<a href="http://www.bccancer.bc.ca">www.bccancer.bc.ca</a>
REIMBURSEMENT AND FORMS: BENEFIT DRUG LIST, CLASS II, BC CANCER AGENCY COMPASSIONATE ACCESS PROGRAM	<a href="http://www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Forms">www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Forms</a>
CANCER DRUG MANUAL	<a href="http://www.bccancer.bc.ca/cdm">www.bccancer.bc.ca/cdm</a>
CANCER MANAGEMENT GUIDELINES	<a href="http://www.bccancer.bc.ca/CaMgmtGuidelines">www.bccancer.bc.ca/CaMgmtGuidelines</a>
CANCER CHEMOTHERAPY PROTOCOLS, PRE-PRINTED ORDERS, PROTOCOL PATIENT HANDOUTS	<a href="http://www.bccancer.bc.ca/ChemoProtocols">www.bccancer.bc.ca/ChemoProtocols</a>
SYSTEMIC THERAPY PROGRAM POLICIES	<a href="http://www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Policies">www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Policies</a>
SYSTEMIC THERAPY UPDATE	<a href="http://www.bccancer.bc.ca/HPI/ChemotherapyProtocols/stupdate">www.bccancer.bc.ca/HPI/ChemotherapyProtocols/stupdate</a>

CONTACT INFORMATION	<a href="http://www.bccancer.bc.ca">www.bccancer.bc.ca</a>	<a href="mailto:bulletin@bccancer.bc.ca">bulletin@bccancer.bc.ca</a>
BC CANCER AGENCY .....	(604) 877-6000 .....	Toll-Free 1-(800) 663-3333
PROVINCIAL SYSTEMIC THERAPY PROGRAM .....	Ext 2247 .....	<a href="mailto:mclin@bccancer.bc.ca">mclin@bccancer.bc.ca</a>
COMMUNITIES ONCOLOGY NETWORK BUSINESS AFFAIRS.....	Ext 2744 .....	<a href="mailto:david.leung@bccancer.bc.ca">david.leung@bccancer.bc.ca</a>
UPDATE EDITOR .....	Ext 2288 .....	<a href="mailto:mdelemos@bccancer.bc.ca">mdelemos@bccancer.bc.ca</a>
COMMUNITIES ONCOLOGY NETWORK PHARMACY EDUCATORS...	.....	<a href="http://www.bccancer.bc.ca/RS/CommunitiesOncologyNetwork/Educators/Pharmacists/cap_bcca@bccancer.bc.ca">www.bccancer.bc.ca/RS/CommunitiesOncologyNetwork/Educators/Pharmacists/cap_bcca@bccancer.bc.ca</a>
COMPASSIONATE ACCESS PROGRAM OFFICE .....	Ext 6277 .....	<a href="mailto:cap_bcca@bccancer.bc.ca">cap_bcca@bccancer.bc.ca</a>
DRUG INFORMATION .....	Fax (604) 708-2026	
EDUCATION RESOURCE NURSE .....	Ext 6275 .....	<a href="mailto:druginfo@bccancer.bc.ca">druginfo@bccancer.bc.ca</a>
NURSING PROFESSIONAL PRACTICE .....	Ext 2638 .....	<a href="mailto:nursinged@bccancer.bc.ca">nursinged@bccancer.bc.ca</a>
LIBRARY/CANCER INFORMATION.....	Ext 2623 .....	<a href="mailto:ilundie@bccancer.bc.ca">ilundie@bccancer.bc.ca</a>
OSCAR HELP DESK .....	1-(888)-675-8001.....	<a href="mailto:requests@bccancer.bc.ca">requests@bccancer.bc.ca</a>
PHARMACY CHEMOTHERAPY CERTIFICATION .....	Ext 8003	
PHARMACY PROFESSIONAL PRACTICE .....	1-(888)-355-0355.....	<a href="mailto:oscar@bccancer.bc.ca">oscar@bccancer.bc.ca</a>
ABBOTSFORD CENTRE (AC) .....	Fax (604) 708-2051	
CENTRE FOR THE SOUTHERN INTERIOR (CCSI) .....	(250) 712-3900 .....	<a href="mailto:rxchemocert@bccancer.bc.ca">rxchemocert@bccancer.bc.ca</a>
FRASER VALLEY CENTRE (FVCC) .....	Ext 686741	
VANCOUVER CENTRE (VCC).....	(250) 519.5574 .....	<a href="mailto:jkippen@bccancer.bc.ca">jkippen@bccancer.bc.ca</a>
VANCOUVER ISLAND CENTRE (VICC) .....	(604) 851-4710 .....	Toll-free: 1-(877) 547-3777
	(250) 712-3900 .....	Toll-Free 1-(888) 563-7773
	(604) 930-2098 .....	Toll-Free 1-(800) 523-2885
	(604) 877-6000 .....	Toll-Free 1-(800) 663-3333
	(250) 519-5500 .....	Toll-Free 1-(800) 670-3322

### Editorial Review Board

Mário de Lemos, PharmD, MSc (Oncol) (Editor)  
 Caroline Lohrisch, MD  
 Johanna Den Duyf, MA  
 Poonam Kothare (Editorial clerk)

Judy Oliver, BScN, MEd  
 Beth Morrison, MLS  
 Jaya Venkatesh, MHA, CMA  
 Susan Walisser, BSc (Pharm)