



# Systemic Therapy Update

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  - Website Resources
- FAX request form and IN TOUCH phone list are provided if additional information is needed.

## EDITOR'S CHOICE

### 2005/06 NEW TREATMENT POLICY ANNOUNCEMENTS

The Provincial Systemic Therapy Program of the BC Cancer Agency is pleased to announce the funding of a number of new treatment programs. These programs will be implemented once the relevant treatment protocols, patient education materials and pre-printed orders have been developed by the Provincial Tumour Groups, the Provincial Pharmacy and the Regional Cancer Centres. Implementation of the new programs will be announced in the Systemic Therapy Update and the relevant supporting documentation will be made available on the BC Cancer Agency web site ([www.bccancer.bc.ca](http://www.bccancer.bc.ca)).

### CURATIVE/ADJUVANT PROTOCOLS

Tumour Group	Program	Special Application Process	Projected implementation date
<b>Breast</b>	<b>Anastrozole</b> for adjuvant therapy in postmenopausal women with high risk breast cancer - ER+PgR- subset or contraindications to tamoxifen only	<b>class I</b>	July 2005  Pending development of management guidelines and plan for communication with potential patients by Tumour Group
<b>Breast</b>	<b>Tamoxifen</b> followed by <b>exemestane</b> each for 2-3 years (total of 5 years treatment) in postmenopausal women with hormone-positive invasive breast cancer	<b>tamoxifen class I, exemestane class I</b>	July 2005  Pending development of management guidelines by Tumour Group
<b>CNS</b>	<b>Temozolomide</b> in concurrent and adjuvant treatment of malignant gliomas. (CNAJTMZ)	<b>class II</b>	June 2005  Pending development of PPPO by Tumour Group
<b>GI</b>	<b>Capecitabine</b> for adjuvant high-risk resected colon cancers	<b>capecitabine class II</b>	July 2005  Pending development of management guidelines, protocol and PPPO by Tumour Group
<b>GU</b>	<b>Carboplatin</b> in adjuvant Stage I seminomatous germ cell cancer (GUSCARB)	<b>carboplatin class I</b>	implemented Mar 2005  Tumour group to revise management guidelines
<b>Lung</b>	<b>Cisplatin</b> and <b>vinorelbine</b> (LUAJNP) or <b>Carboplatin</b> and <b>paclitaxel</b> (LUAJCAT) for resected adjuvant non-small cell lung cancer.	<b>all class I</b>	June 2005

### NON-CURATIVE/ADJUVANT PROTOCOLS

Tumour Group	Program	Special Application Process	Projected implementation date
<b>Breast</b>	<b>Gemcitabine</b> and <b>paclitaxel</b> in metastatic breast cancer	<b>paclitaxel class I</b>  <b>gemcitabine class II</b>	July 2005  Pending development of protocol and PPPO by Tumour Group

<b>Breast</b>	<b>Trastuzumab and docetaxel</b> for metastatic breast cancer	<b>docetaxel class II</b>  <b>trastuzumab class II</b>	July 2005  Pending development of management guidelines, protocol and PPPO by Tumour Group
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**PROTOCOLS NOT BEING FUNDED AT THIS TIME**

<b>Tumour Group</b>	<b>Program</b>	<b>Comments</b>	
		<b>Priorities and Evaluation Committee</b>	<b>Provincial Systemic Therapy Program</b>
<b>GI</b>	<b>FOLFOX</b> for adjuvant therapy in stage III colon cancer.	<p>The proposal has provided Level 1 evidence to support the use of FOLFOX over bolus 5FU/LV as adjuvant therapy of stage III colon cancer. It should be noted that this is based on benefit on DFS and not OS. There is some evidence to suggest that a small benefit in DFS may also be seen in stage II colon cancer. The extrapolated benefit to rectal cancer and stage IV colorectal cancer rendered NED is not well established.</p> <p>Marginal: Incremental cost-effectiveness ratio prohibitive for no survival gain. In the absence of any gain in survival, it is considerably more cost-effective to treat patients at relapse with discounted and inflated dollars.</p>	This will be funded, for Stage III colon cancer only, when confirmation of budget received from PHSA. At present, this treatment program is not available.
<b>GI</b>	<b>Irinotecan</b> as second line treatment in metastatic gastroesophageal adenocarcinoma.	<p>The data on the proposed 2<sup>nd</sup> line use of IR or FUIR is supported by one phase 2 study which has an acceptable toxicity profile.</p> <p>Marginal: Restrict to adenocarcinoma only; second line intervention. Proceed to ranking and economic analysis.</p>	Limited access via undesignated process pending further funding available.
<b>Lung</b>	<b>Gefitinib</b> as <u>first line</u> treatment of select adenocarcinomas with bronchioalveolar features.	This direct evidence of the benefit of gefitinib as a first line agent in the treatment of these patients needs to be presented before this therapy can be incorporated into practice.	Limited access via undesignated process

## OTHER CHANGES

Tumour Group	Program	Special Application Process	Projected implementation date
Head & Neck	<b>Thyrotropin alfa</b> for radioiodine imaging follow-up for thyroid cancer patients with contraindication to thyroxine withdrawal (HNSTH)	Changed to class I	June 2005
Leukemia	<b>Imatinib</b> as 1 <sup>st</sup> and 2 <sup>nd</sup> line treatment of CML (LKCMLI)	Changed to class II	June 2005
Multiple	<b>Interferon</b> for multiple indications	Changed to class I	June 2005
Multiple	<b>Paclitaxel</b> for multiple indications	Changed to class I	June 2005

### HIGHLIGHTS OF PROTOCOL CHANGES

Several changes are introduced to the protocols. All the changes are **effective 1 June 2005**.

**New Protocols** Several newly funded regimens have been introduced:

- Concomitant and adjuvant **temozolomide** with radiation therapy can be used for newly diagnosed **malignant gliomas** (CNAJTMZ, previously UCNAJTMZ).
- Two new adjuvant treatment programs for resected **non-small cell lung cancer** have also been introduced, with combination of **carboplatin** and **paclitaxel** (LUAJCAT) and **cisplatin** and **vinorelbine** (LUAJNP).
- A new protocol using combination of **BCG** and **interferon** has been introduced (GUBCGIFN) as palliative therapy of **bladder cancer**. This intravesical treatment program is aimed for patients with superficial high-grade transitional cell carcinoma of the bladder which has progressed despite previous BCG therapy.

**Change in Benefit Status** Protocols from several tumour sites have undergone revisions. One major change is the removal of class II application requirement for **paclitaxel** and **interferon** from all current protocols. The change in paclitaxel affects several tumour sites, mainly **Breast** and **Gynecology**, while that of interferon affects the **Genitourinary**, **Leukemia**, **Lung**, **Lymphoma** and **Melanoma** tumour sites. Finally, requirement for case-by-case approval for **imatinib** is no longer needed in the setting of first or second line therapy of chronic myelogenous **leukemia**.

**Revised Protocols** Major changes in **breast cancer** protocols include clarification of the **age limit** of 60 years in several adjuvant regimens, management of **paclitaxel hypersensitivity**, and an update on **cardiac toxicity with trastuzumab**. Two protocols for **gynecological malignancies** have been extensively updated, namely the treatment of relapsed/progressive ovarian, fallopian tube or primary peritoneal cancer with **etoposide** (GOOVETO) and treatment of high risk gestational trophoblastic tumours using **cisplatin**, **etoposide**, **actinomycin**, **methotrexate** and **leucovorin** (GOTDHR).

### UPDATE FROM THE 2005 AMERICAN SOCIETY OF CLINICAL ONCOLOGY (ASCO) ANNUAL MEETING

Results from several major randomised controlled trials involving the addition of monoclonal antibody and targeted drug therapies to chemotherapy were reported at the ASCO Annual Meeting on 13-17 May. Several trials reported that adjuvant monoclonal antibody therapy may improve disease free and overall survival in women with breast cancer. Trastuzumab was used in three of these trials while bevacizumab was used in one of them. Bevacizumab is a VEGF inhibitor that has been shown to inhibit angiogenesis. It is currently not available in Canada.

Bevacizumab was also reported to improve overall survival in patients with advanced non-small cell lung cancer and colorectal cancer. Erlotinib – a EGFR tyrosine kinase inhibitor – was also reported to improve overall

survival in patients with unresectable pancreatic cancer from a NCIC phase III trial. Erlotinib is currently not available in Canada but may be obtained via Health Canada Special Access Programme.

### Breast Cancer

The **ECOG study E2100** involved the use of paclitaxel with or without bevacizumab – a VEGF inhibitor – as first-line therapy in 715 patients with locally recurrent or metastatic breast cancer. Paclitaxel was given as 90 mg/m<sup>2</sup> IV on days 1, 8 and 15, and bevacizumab as 10 mg/kg IV on days 1 and 15. Treatment was repeated every 28 days. Patients were generally HER-2 negative. After a median follow-up of 55 months, addition of bevacizumab was associated with improved progression free survival from about 6 to 11 months (HR 0.50, p < 0.001). Although the median was not reached, there was also significant improvement in overall survival (HR 0.67, p = 0.01). Treatment with bevacizumab was associated with significantly more grade 3/4 hypertension (13% vs. 0%), proteinuria (2.4% vs. 0%) and peripheral neuropathy (21% vs. 14%) than treatment with paclitaxel alone.

Joint analysis of two studies – **NSABP-B-31 and NCCTG-N9831** – was reported. Both studies involved the use of doxorubicin and cyclophosphamide followed by paclitaxel with or without trastuzumab as adjuvant therapy in 3351 patients with high risk, HER-2 positive breast cancer. Doxorubicin 60 mg/m<sup>2</sup> IV and cyclophosphamide 600 mg/m<sup>2</sup> IV were given every 3 weeks for 4 cycles (standard AC regimen), followed by paclitaxel 175 mg/m<sup>2</sup> IV every 3 weeks for 4 cycles or 80 mg/m<sup>2</sup> IV weekly for 12 cycles. Trastuzumab was given after completion of paclitaxel treatment as a 4 mg/kg IV loading dose then weekly at a dose of 2 mg/kg for 51 cycles. After a median follow-up of 2 years, addition of trastuzumab was associated with an improved 3-year disease free survival from 75% to 87% (HR 0.48, p = 3 x 10<sup>-12</sup>). There was also a statistically significant improvement in 3-year overall survival from 92% to 94% (HR 0.67, p 0.015). Addition of trastuzumab however was associated with significantly more grade 3/4 cardiac toxicity (4.0% vs. 0.6%).

The NCCTG-N9831 study also involved the comparison between sequential and concurrent trastuzumab. Standard AC regimen was followed by paclitaxel and trastuzumab as adjuvant therapy in 1825 patients with high risk, HER-2 positive breast cancer. Paclitaxel was given 80 mg/m<sup>2</sup> IV weekly for 12 cycles. Trastuzumab was given as 4 mg/kg IV loading dose then at a weekly dose of 2 mg/kg IV for 51 cycles, given sequentially or concurrently with paclitaxel. After a median follow-up of 1.5 years, concurrent trastuzumab was associated with improved disease free survival (HR 0.64, p = 0.011). Improvement in overall survival was not statistically significant at this point (HR 0.74, p = 0.27). Incidence of left ventricular dysfunction was similar between sequential (2.2%) and concurrent trastuzumab (3.3%).

The **HERA** trial involved the comparison between trastuzumab and observation after at least 4 cycles of standard adjuvant chemotherapy in 3387 patients with high risk, HER-2 positive breast cancer. Trastuzumab was given as 8 mg/kg IV loading dose then 6 mg/kg every 3 weeks for one year. After a median follow-up of 1 year, addition of trastuzumab was associated with improved 2-year disease free survival from 77% to 86% (HR 0.54, p < 0.0001). Overall survival was similar at this point (95% vs. 96%, HR 0.76, p = 0.26). Addition of trastuzumab was associated with a higher incidence of left ventricular dysfunction (2.2% vs. 7.1%).

### Non-Small Cell Lung Cancer (NSCLC)

The **ECOG study E4599** involved the use of carboplatin and paclitaxel with or without bevacizumab as first-therapy in 878 patients with advanced non-squamous cell NSCLC ([Late breaking abstract #4](#)). Carboplatin AUC 6 and paclitaxel 200 mg/m<sup>2</sup> were given IV every 3 weeks for 6 cycles. Bevacizumab was given as 15 mg/kg every 3 weeks concurrently with carboplatin and paclitaxel, and continued until progressive disease or intolerable toxicity. With about 72% of deaths at the time of analysis, the addition of bevacizumab was associated with a small but statistically significant increase in overall survival from 10.2 to 12.5 months (HR 0.62, p < 0.0001) and in progression free survival from 4.5 to 6.4 months (HR 0.62, p < 0.0001). Bevacizumab was also associated with improvement in objective response rate from 10% to 27% (p < 0.0001). However, addition of bevacizumab was associated with a higher incidence of grade 3/4 hemorrhage (1.0% vs 4.1%), and thromboembolism (3% vs. 3.8%), and grade 4/5 neutropenia (16.4% vs. 24%). Other toxicities included hypertension (6%) and hemoptysis (1.3%).

### Gastrointestinal Cancer

The **ECOG Study E3200** involved the use of FOLFOX4 with or without high dose bevacizumab as second-line therapy in 546 patients with metastatic colorectal cancer ([Abstract #2](#)). Patients were previously treated with a fluoropyrimidine and an irinotecan-based regimen. FOLFOX4 consisted of a regimen of oxaliplatin 85 mg/m<sup>2</sup> IV, fluorouracil 400 mg/m<sup>2</sup> bolus then 600 mg/m<sup>2</sup> continuous infusion for 22 hours, and leucovorin 200 mg/m<sup>2</sup> IV every 2 weeks. Bevacizumab was given as 10 mg/kg IV every 2 weeks. The median number of treatment cycles was 10. After a median follow-up of 18.7 months, addition of bevacizumab was associated with improved progression free survival from about 5 to 7 months (p < 0.0001). There was also significant improvement in overall survival from about 11 to 13 months (HR 0.76, p = 0.0018). Addition of bevacizumab however was associated with more grade 3/4 hypertension (3% vs. 7%), bleeding (~1% vs. 3%), peripheral neuropathy (10% vs. 16%), vomiting and bowel perforation (0% vs. 1.1%).

The **PA.3 Study** involved the use of gemcitabine with or without erlotinib as first-line therapy in 569 patients with advanced pancreatic cancer ([Abstract #1](#)). Gemcitabine was given as 1000 mg/m<sup>2</sup> IV weekly for 7 out of 8 weeks then weekly for 3 out of 4 weeks. Erlotinib was given orally as 100 mg daily, escalating to 150 mg daily in 48 patients. With about 85% of deaths at the time of analysis, the addition of erlotinib was associated with a small but statistically significant increase in overall survival from 5.9 to 6.4 months (HR 0.81, p = 0.025) and in progression free survival from 3.6 to 3.8 months (HR 0.76, p = 0.003). Erlotinib was also associated with improvement in objective response rate from 49.2% to 57.5%. Subset analyses suggested that erlotinib was most effective for men, patients with poor performance status, those younger than 65, and those with metastatic disease. An increase in grade 1/2 rash, diarrhea and hematological toxicity was seen with erlotinib. Rates of grade 3 and 4 toxicity were similar in both arms.

### **BENEFIT DRUG LIST**

The following changes to the Benefit Drug List are **effective 1 June 2005**:

<i>Drug</i>	<i>Indication</i>	<i>Benefit status</i>
Aldesleukin	pediatric AML or myelodysplastic syndrome treated on the CCG 2961 study or its companion study	deleted
Amifostine	high risk germ cell tumour treated on the CCG P9749 study (Pilot Intergroup study of high dose cisplatin, etoposide and bleomycin combined with amifostine)	deleted
BCG	palliative therapy for BCG-refractory superficial high-grade transitional cell carcinoma bladder with BCG and interferon (GUBCGIFN)	added as Class I
Imatinib	therapy for chronic myeloid leukaemia using imatinib (LKCMLI)	changed to Class II
Interferon	all previous class II indications	changed to Class I
	palliative therapy for BCG-refractory superficial high-grade transitional cell carcinoma bladder with BCG and interferon bladder cancer (GUBCGIFN)	added as Class I
Paclitaxel	<ul style="list-style-type: none"><li>▪ all previous class II indications</li><li>▪ adjuvant carboplatin and paclitaxel following resection of stage I, II and IIIA non-small cell lung cancer (LUAJCAT)</li></ul>	<ul style="list-style-type: none"><li>▪ changed to Class I</li><li>▪ added as Class I</li></ul>
Temozolomide	concomitant and adjuvant temozolomide for newly diagnosed malignant gliomas (CNAJTMZ)	added as Class II
Thyrotropin	radioiodine imaging follow-up for thyroid cancer patients with contraindication to thyroxine withdrawal (HNTSH)	changed to Class I

<i>Drug</i>	<i>Indication</i>	<i>Benefit status</i>
Topotecan	<ul style="list-style-type: none"> <li>▪ pediatric patients with relapsed solid tumours treated on the CCG 09713 study (phase II study of continuous 21 day infusion of topotecan)</li> <li>▪ pediatric patients with relapsed leukemia treated on the CCG 09714 study (phase II study of oral topotecan)</li> <li>▪ pediatric patients with refractory meningeal malignancies treated on the CCG P9962 study (phase II study of intrathecal topotecan)</li> </ul>	deleted

### FOCUS ON INTERFERON-ALPHA

Interferons are a group of naturally occurring proteins, classed as a biologic response modifier, with complex antiviral, antineoplastic and immunomodulating activities.<sup>1,2</sup> There are three classes of interferon (IFN); alpha, beta and gamma.<sup>3</sup> This article will focus on IFN-alpha.

There are at least 23 structurally similar subtypes of human IFN-alpha that have been identified.<sup>2</sup> Two formulations of IFN-alpha are currently produced by recombinant DNA technology; IFN-alpha 2a and IFN-alpha 2b. These two IFN-alpha subtypes differ by a single amino acid substitution. The clinical significance of this difference has not been established, either therapeutically or in toxicology.<sup>2,3</sup> The majority of clinical data available is with IFN-alpha 2b. Currently, only IFN-alpha 2b is produced commercially in Canada as Intron-A®, a product of Schering Canada Inc. As of fall 2004, Hoffman-La Roche began to discontinue their line of IFN-alpha 2a (Roferon-A®). It will no longer be available upon exhaustion of stock.

Endogenous IFN-alpha is produced principally in response to viral infection. The precise mechanism of action is unclear, but it is thought to be a complex process with substantial interrelated activities. The effects of interferons appear to be from a cascade of biologic modulation and pharmacologic effects involving many cell functions including modulation of cell differentiation, modulation of cellular transcription and translation, reduction in oncogene expression, and direct antiproliferative and antineoplastic activity.

A drug with both antiviral and cytotoxic effects has great potential for numerous indications. IFN was first discovered in the late 1950's as a potential antiviral agent. With the introduction of recombinant DNA technology in the late 1970's, which allowed large-scale production of purified substrates, IFN use has now expanded to a variety of malignancies and virologic diseases. It has been stated that the full therapeutic potential of IFN-alpha is yet to be realized.<sup>4</sup> The challenge for pharmacy is to avoid the potential for any medication error, when dealing with a drug that is used in many different protocols, with different dosage forms.

#### Use at the BC Cancer Agency

Within the BC Cancer Agency, IFN-alpha is now a Class I Benefit drug, (5) with approval for use only in:

<ul style="list-style-type: none"> <li>▪ Basal cell carcinoma</li> <li>▪ Chronic myelogenous leukemia (CML)</li> <li>▪ Lymphoproliferative disease</li> <li>▪ Myeloproliferative disease</li> </ul>	<ul style="list-style-type: none"> <li>▪ Post-bone marrow transplantation</li> <li>▪ Metastatic renal cell carcinoma</li> <li>▪ Multiple myeloma</li> </ul>
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For these indications, IFN-alpha 2a and IFN-alpha 2b are considered to be clinically interchangeable by the BC Cancer Agency. IFN-alpha 2b is also approved for use in the adjuvant therapy of melanoma patients with palpable lymph nodes or fully resected recurrent disease in lymph nodes (SMAJIFN).<sup>6</sup> BCCA does not reimburse the use of IFN for hepatitis or Kaposi's sarcoma.

The BC Cancer Agency has other protocol summaries that use IFN-alpha. IFN and cytarabine can be used chronic myeloid leukemia (CML) in patients who are not candidates for sibling donor stem cell transplants

(protocol CMLIFNCYT).<sup>7</sup> In advanced renal cell carcinoma, INF-alpha is used subcutaneously, as outlined in protocol GUKIFN.<sup>8</sup> IFN is occasionally used as a single agent in the palliative or symptomatic management of lymphoproliferative disease (protocol LYPALL).<sup>9</sup>

Recently, IFN alpha has been introduced for the treatment of BCG-refractory bladder cancer (see GUBCGIFN under Highlights of New and Revised Protocols), with a dose of 50 MIU used in combination with low dose BCG, instilled into the bladder on a weekly basis, for 6-8 treatments.<sup>10</sup> Use in other conditions (eg, carcinoid tumour<sup>11</sup> would require approval via the undesignated request process.

### Side Effects

General side effects of IFN-alpha 2b include nausea, flu-like illness, fatigue and emotional changes.<sup>12</sup> Both acute and chronic toxicities are of particular concern with high dose treatment, as in the SMAJIFN protocol. In addition to those side effects already described, anorexia, weight loss, depression, neutropenia and elevated liver enzymes can significantly affect the patient's quality of life. Continued assessment and monitoring is essential to ensuring safety, as these toxicities may be severe and life threatening.<sup>13</sup>

IFN-alpha 2b used with BCG appears to be tolerated equally well as treatment with BCG alone.<sup>10</sup> Side effects reported include local cystitis, transient hematuria, flu-like symptoms and fever.

With subcutaneous use, patient teaching is required on the use of the multi-dose pen. Teaching elements include rotation of injection site, single use needles and correct setting of dose. As an aid, Schering has produced a patient education video titled "Self-injection with Intron-A: Multi-Dose Pen".<sup>14</sup>

### Product Selection

With numerous IFN products available in a variety of strengths, it is important that the pharmacist selects the correct product form and strength for the prescribed protocol, route of administration and dose. Below is a summary of products available from Schering, with stability as per BCCA standards.

<b>Interferon Alpha-2b (Intron-A® by Schering)</b>			
<b>Product Form</b>	<b>Dose Supplied</b>	<b>Strength</b>	<b>Stability</b>
Lyophilized powder with diluent (2 mL SWI)	10 MIU/vial		As per manufacturer guidelines
	18 MIU/vial		
Ready to Use Solution	10 MIU/vial	1mL vial (10 MIU/mL)	4 weeks after first puncture
	18 MIU/vial	3 mL vial (6 MIU/mL)	
	25 MIU/vial	2.5 mL vial (10 MIU/mL)	
Multi-dose pen	18 MIU	0.3 MIU/click or 15 MIU/mL	4 weeks after first use or max of 12 doses, whichever comes first
	30 MIU	0.5 MIU/click or 25 MIU/mL	
	60 MIU	1.0 MIU/click or 50 MIU/mL	

Generally speaking, the following summary can be used as a guideline in selecting the appropriate product for route of administration:

For **subcutaneous** administration of IFN-alpha, the multi-dose pen is generally used. Prior to availability of the pen, the ready to use solution was used and can still be, if so desired by the patient. The majority of patients choose the pen for ease of use. For **intermittent IV** administration, the ready to use solution is generally used. For **bladder instillation** the lyophilized powder is used with BCG, as the ready to use solution has a preservative that could potentially decrease the effectiveness of the BCG.<sup>15</sup>

In summary, IFN-alpha is used within the BC Cancer Agency for a variety of indications, in approved treatment protocol summaries and undesignated use. A variety of product forms exist for IFN-alpha 2b, which creates a challenge for the pharmacist in selecting the correct product for the prescribed therapy, to ensure medication safety.

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References

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2. McEvoy GK, editor. American Hospital Formulary Services. Bethesda (MD): American Society of Health-System Pharmacists; 2004.
3. Corelli, RL, editor. Acute and Chronic Hepatitis. In: Young LY, Koda-Kimble MA, editors. Applied therapeutics: the clinical use of drugs. 6<sup>th</sup> ed. Vancouver (WA): Applied Therapeutics; 1995. p.62-12.
4. Pfeller, LM, et al. Biological properties of recombinant alpha-interferons: 40<sup>th</sup> anniversary of the discovery of interferons. Cancer Res. 1998 Jun 15;58(12):2489-99
5. Class II drug registration form. Vancouver: BC Cancer Agency Systemic Therapy Program (Dec. 1, 2004).
6. BCCA protocol SMAJIFN (BCCA protocol summary for adjuvant therapy of high risk malignant melanoma with high dose interferon (HDIFN)  $\alpha$ -2b). Vancouver: BC Cancer Agency (Nov. 1, 2002).
7. BCCA protocol CMLIFNCYT (BCCA protocol summary for therapy of chronic myeloid leukemia using interferon and cytarabine). Vancouver: BC Cancer Agency (Nov. 1, 2000).
8. BCCA protocol GUKIFN (BCCA protocol summary for alpha-interferon (a-IFN) for advanced renal cell carcinoma). Vancouver: BC Cancer Agency (Nov. 1, 1999).
9. BCCA protocol LYPALL (BCCA protocol summary for lymphoma palliative chemotherapy). Vancouver: BC Cancer Agency (June 1, 2004).
10. O'Donnell, M, et al. Salvage intravesical therapy with interferon-alpha2b plus low dose bacillus calmette-guerin is effective in patients with superficial bladder cancer in whom bacillus calmette-guerin alone previously failed. Journal of Urology 166, 1300-1305, Oct 2001.
11. Email communication, Laurel Kovacic, Acting Pharmacoeconomic Pharmacist, Dec. 8, 2004.
12. de Lemos ML, editor. BC Cancer Agency cancer drug manual. Vancouver: BC Cancer Agency; 2001 [cited 2004 Dec 16]. Available from <http://www.bccancer.bc.ca/HPI/DrugDatabase/DrugIndexPt/Interferon.htm>
13. Kirkwood, JM, et al. Mechanisms and management of toxicities associated with high-dose interferon alfa-2b therapy. Journal of Clinical Oncology, vol 20, No 17 (September 1), 2002: 3703-3718
14. Self-Injection with Intron-A: Multi-Dose Pen. Sept. 12,2004, Schering Canada Inc. (video)
15. Letter from S. Dao, B. Pharm., D. Mgmt, Project Manager-Medical Services, Schering Canada Inc., July 9, 2003.

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## NURSING UPDATE

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### Continuing Competency in Chemotherapy

In April we mailed letters to all provincial nurses who had been chemo certified for at least one year. We asked that you submit evidence of having completed the 2004 requirements for Continuing Competency in Chemotherapy. If you have not already returned those forms please do so ASAP.

### Article of the month:

Leonard, M., Hannelef, K., and Smith, G. (2004). Fertility considerations, counselling, and semen cryopreservation for males prior to the initiation of cancer therapy. *Clinical Journal of Oncology Nursing*. 8(2), 127-132. <http://www.ons.org/publications/journals/CJON/welcome.shtml>

### Web-Based Continuing Education Opportunity:

#### “Oncology Supportive Care Quarterly: Focused on Nursing Issues in the Care of Oncology Patients”.

This continuing education program offered through the Oncology Education Services clarifies key facts about the elderly and chemotherapy; describes the issues of decline in bone marrow function; outlines key points in geriatric assessment; and clearly discusses key issues related to supportive care of older persons receiving chemotherapy. [http://www.oesweb.com/print\\_print\\_all.asp](http://www.oesweb.com/print_print_all.asp)

## Chemotherapy Nurse Certification

Congratulations to the following nurses who have become chemotherapy certified since August 2004:

### Regional Cancer Center Nurses

Salima Dharamsi  
Rachelle Wawara  
Darline Vogt  
Jean Larioza  
Daniel Scarborough  
TC Tan  
Anne King  
Rowena Nelson  
Lesley Forrest

### Community Cancer Service Nurses

Loretta Mehr, Smithers  
Meghan Smaha, Terrace  
Darlene Irvine, Dawson Creek  
Megan Ouelette-Johannsen, Dawson Creek  
Mary-Ann Etchart, Kamloops  
Shauna Archibald, Ridge Meadows  
Cheri Turcot, Kelowna  
Pearl Dutoff, Kootenay Lake  
Roni Mould, Vernon  
Lauren Flemming, Kelowna  
Corinna Werbecky, Prince George  
Dessislava Gyokova, North Shore

### Community Cancer Center Nurses

Diane Chow, Richmond  
Hershey Jaranilla, Richmond  
Joy Barnes, Chilliwack

### Community Hospital Nurses

Deb MacSweeny, Squamish  
Linda Woods, Squamish  
Donna Mears, Victoria  
Gea Van Stam-van Der Waals, Kelowna  
Patti Randle, 100 Mile House

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## CANCER DRUG MANUAL

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**Etoposide Monograph and Patient Information** have been completely revised.

**Mercaptopurine and Thioguanine Monographs and Patient Information** have been revised to clarify issues regarding the effect of food on oral absorption.

**Amifostine Monograph** has been revised to include emergent evidence on the use of IV push administration to reduce severe nausea and vomiting.

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## PATIENT EDUCATION

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**Revised Patient Handouts on Cancer Drugs** The patient information handouts for **Etoposide, Mercaptopurine** and **Thioguanine** have been revised. See under Cancer Drug Manual for more details.

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## LIST OF NEW AND REVISED PROTOCOLS

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The **BC Cancer Agency Protocol Summaries** are revised on a periodic basis. New and revised protocols for this month are listed below. Protocol codes for treatments requiring “Undesignated Indication” approval are prefixed with the letter **U**.

New protocol:

- **GUBCGIFN** new: Palliative therapy for BCG-refractory superficial high-grade transitional cell carcinoma bladder with BCG and interferon.

Revised protocols:

- **BRAJACT** revised (*paclitaxel class II requirement removed*): Adjuvant therapy for breast cancer using doxorubicin and cyclophosphamide followed by paclitaxel

- **BRAJACTG** revised (*paclitaxel class II requirement removed*): Adjuvant therapy for breast cancer using dose dense therapy: doxorubicin and cyclophosphamide followed by paclitaxel
- **BRAJCEF** revised (*age limit eligibility revised*): Adjuvant therapy for breast cancer using cyclophosphamide, epirubicin and fluorouracil
- **BRAJCEFG** revised (*age limit eligibility revised*): Adjuvant therapy for breast cancer using cyclophosphamide, epirubicin, fluorouracil and filgrastim (G-CSF)
- **BRAJFEC** revised (*age limit and poor tolerance to BRAJCEF revised in eligibility*): Adjuvant therapy for breast cancer using fluorouracil, epirubicin and cyclophosphamide
- **BRAVDOC** revised (*number of treatment cycles clarified*): Palliative therapy for metastatic breast cancer using docetaxel (Taxotere®)
- **BRAVTAX** revised (*paclitaxel hypersensitivity management added, paclitaxel class II requirement removed*): Palliative therapy for metastatic breast cancer using paclitaxel
- **BRAVTPC** revised (*paclitaxel hypersensitivity management added, paclitaxel class II requirement removed cardiac toxicity in Precautions updated, reference added*): Palliative therapy for metastatic breast cancer using trastuzumab (Herceptin®), paclitaxel and carboplatin as first-line treatment for recurrent breast cancer refractory to anthracycline chemotherapy
- **BRAVTR** revised (*cardiac toxicity in Precautions updated, reference added*): Palliative therapy for metastatic breast cancer using trastuzumab (Herceptin®)
- **BRAVTRAP** revised (*paclitaxel hypersensitivity management added, paclitaxel class II requirement removed cardiac toxicity in Precautions updated, reference added*): Palliative therapy for metastatic breast cancer using trastuzumab (Herceptin®) and paclitaxel as first-line treatment for recurrent breast cancer refractory to anthracycline chemotherapy
- **BRAVTRNAV** revised (*cardiac toxicity in Precautions updated, reference added*): Palliative therapy for metastatic breast cancer using trastuzumab (Herceptin®) and vinorelbine
- **BRINFCEF** revised (*age limit eligibility revised*): Therapy for inflammatory breast cancer using cyclophosphamide, epirubicin and fluorouracil
- **BRINFCEFG** revised (*age limit eligibility revised*): Therapy for inflammatory breast cancer using cyclophosphamide, epirubicin, fluorouracil and filgrastim (G-CSF)
- **BRLAACD** revised (*age limit eligibility revised*): Treatment of Locally advanced breast cancer using doxorubicin and cyclophosphamide followed by docetaxel (Taxotere®)
- **BRLACEF** revised (*age limit eligibility revised*): Therapy for locally advanced breast cancer using cyclophosphamide, epirubicin and fluorouracil
- **BRLACEFG** revised (*age limit eligibility revised*): Therapy for locally advanced breast cancer using cyclophosphamide, epirubicin, fluorouracil and filgrastim (G-CSF)
- **CMLIFNCYT** revised (*interferon class II requirement removed*): Therapy of chronic myeloid leukemia using interferon and cytarabine
- **CNAJTMZ** revised (*undesignated requirement removed*): Concomitant and adjuvant temozolomide for newly diagnosed malignant gliomas
- **GOCXCAT** revised (*paclitaxel class II requirement removed*): Primary treatment of advanced/recurrent non-small cell cancer of the cervix with carboplatin and paclitaxel in ambulatory care settings
- **GOENDCAT** revised (*paclitaxel class II requirement removed*): Treatment of primarily advanced or recurrent endometrial cancer using carboplatin and paclitaxel (GO 95 01)
- **GOOVCATM** revised (*paclitaxel class II requirement removed*): Primary treatment of invasive epithelial ovarian, fallopian tube and primary peritoneal cancer, with no visible residual tumour (moderate-high risk) using paclitaxel and carboplatin
- **GOOVCATR** revised (*paclitaxel class II requirement removed*): Second line treatment using paclitaxel and carboplatin for epithelial ovarian cancer relapsing after primary treatment
- **GOOVCATX** revised (*paclitaxel class II requirement removed*): Primary treatment of visible residual (extreme risk) invasive epithelial ovarian cancer in ambulatory care settings using paclitaxel and carboplatin
- **GOOVETO** revised (*eligibility, dosing frequency and treatment duration clarified*): Treatment of relapsed/progressive ovarian, fallopian tube or primary peritoneal cancer with etoposide

- **GOOVTA3** revised (*paclitaxel class II requirement removed*): Treatment of progressive, platinum-refractory epithelial ovarian carcinoma, primary peritoneal carcinoma or fallopian tube carcinoma using paclitaxel
- **GOSMCC2** revised (*paclitaxel class II requirement removed*): Treatment of small cell carcinoma of cervix using paclitaxel, cisplatin, etoposide and carboplatin with radiation (GO 95 02)
- **GOTDHR** revised (*completely updated*): Therapy for high risk gestational trophoblastic (GO9103) "MACE" using cisplatin, etoposide, actinomycin D, methotrexate and leucovorin
- **GUKIFN** revised (*interferon class II requirement removed*): Therapy for advanced renal cell carcinoma using alpha-Interferon (a-IFN)
- **HNRAMI** revised (*IV push as alternative administration route added*): Radioprotection in head and neck radiation using amifostine
- **HNTSH** revised (*treatment and tests schedule added, thyrotropin class II requirement removed*): Radioiodine imaging in patients with thyroid cancer using thyrotropin alpha
- **LKCMLI** revised (*undesigned requirement removed*): Therapy for chronic myeloid leukemia using imatinib (Gleevec®)
- **LUAJCAT** revised (*undesigned requirement removed*): Adjuvant carboplatin and paclitaxel following resection of stage I, II and IIIA non-small cell lung cancer
- **LUAJNP** revised (*undesigned requirement removed*): Adjuvant cisplatin and vinorelbine following resection of stage I, II and IIIA non-small cell lung cancer
- **LUAVCAT** revised (*paclitaxel class II requirement removed*): First line treatment of advanced non-small cell lung cancer (NSCLC) with carboplatin and paclitaxel
- **LYPALL** revised (*interferon class II requirement removed*): Lymphoma palliative chemotherapy
- **SMAJIFN** revised (*interferon class II requirement removed*): Adjuvant therapy of high risk malignant melanoma with high dose interferon (HDIFN) alpha-2b

#### **LIST OF NEW AND REVISED PRE-PRINTED ORDERS**

The **INDEX to BC Cancer Agency Pre-printed Orders** are revised on a periodic basis. New and revised pre-printed orders for this month are listed below.

- **BRAJACT** revised (*paclitaxel class II requirement removed*): Adjuvant therapy for breast cancer using doxorubicin and cyclophosphamide followed by paclitaxel
- **BRAJACTG** revised (*paclitaxel class II requirement removed*): Adjuvant therapy for breast cancer using dose dense therapy: doxorubicin and cyclophosphamide followed by paclitaxel
- **BRAVDOC** revised (*number of treatment cycles clarified*): Palliative therapy for metastatic breast cancer using docetaxel (Taxotere®)
- **BRAVTAX** revised (*paclitaxel hypersensitivity management added, paclitaxel class II requirement removed*): Palliative therapy for metastatic breast cancer using paclitaxel
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- **LUAJNP** revised (*undesigned requirement removed*): Adjuvant cisplatin and vinorelbine following resection of stage I, II and IIIA non-small cell lung cancer
- **LUAVCAT** revised (*paclitaxel class II requirement removed*): First line treatment of advanced non-small cell lung cancer (NSCLC) with carboplatin and paclitaxel
- **SMAJIFN** revised (*interferon class II requirement removed*): Adjuvant therapy of high risk malignant melanoma with high dose interferon (HDIFN) alpha-2b

#### **CONTINUING EDUCATION – MARK YOUR CALENDAR**

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- **2-5 October 2005:** Annual Canadian Association of Oncology Nursing Conference, Moncton, New Brunswick ([www.cos.ca/cano](http://www.cos.ca/cano))
  - **23-26 October 2005:** 1<sup>st</sup> International Cancer Control Congress, Pan Pacific Hotel, Vancouver, BC ([www.cancercontrol.org](http://www.cancercontrol.org))
  - **28-30 October 2005:** National Oncology Pharmacy Symposium, Sheraton Wall Centre, Vancouver, BC (<http://capho.ca/>)
  - **3-5 November 2005:** BCCA Annual Cancer Conference, Westin Bayshore 1601 Bayshore Drive, Vancouver, BC

#### **WEBSITE RESOURCES**

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**Reimbursement and Forms:** The current Benefit Drug List, Class II forms and Undesignated Indication Application forms are available on the BC Cancer Agency website under Health Professionals Info, Chemotherapy Protocols, Frequently Used Forms (<http://www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Forms.htm>).

**Cancer Drug Manual** is available on the BC Cancer Agency website [www.bccancer.bc.ca/cdm/](http://www.bccancer.bc.ca/cdm/).

**Cancer Management Guidelines** are available on the BC Cancer Agency website (<http://www.bccancer.bc.ca/CaMgmtGuidelines/>) under Health Professionals Info, Cancer Management Guidelines.

**The Cancer Chemotherapy Protocols** are available on the BC Cancer Agency website ([www.bccancer.bc.ca/ChemoProtocols](http://www.bccancer.bc.ca/ChemoProtocols)) under Health Professionals Info, Chemotherapy Protocols.

**The Cancer Chemotherapy Pre-Printed Orders** are available on the BC Cancer Agency website ([www.bccancer.bc.ca/ChemoProtocols](http://www.bccancer.bc.ca/ChemoProtocols)) under Health Professionals Info, Chemotherapy Protocols. Pre-Printed Orders are posted at the index page of each tumour site.

**Provincial Systemic Therapy Program Policies** are available on the BC Cancer Agency website ([www.bccancer.bc.ca](http://www.bccancer.bc.ca)) under Health Professionals Info, Chemotherapy Protocols, Policies and Procedures.

**The Unconventional Cancer Therapies Manual** is available on the BC Cancer Agency website [www.bccancer.bc.ca](http://www.bccancer.bc.ca) under Patient/Public Info, Unconventional Therapies.

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# BC CANCER AGENCY SYSTEMIC THERAPY UPDATE REQUEST FORM

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## UPDATES Please Fax-Back information below:

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<input type="checkbox"/> All items for <b>June 2005 (Vol 8 № 6)</b>					
<u>Cancer Drug Manual Monographs</u> : (also available on our website <a href="http://www.bccancer.bc.ca">www.bccancer.bc.ca</a> )					
<u>Patient Education Handout</u> : (also available on our website <a href="http://www.bccancer.bc.ca">www.bccancer.bc.ca</a> )					
<input type="checkbox"/> etoposide		<input type="checkbox"/> mercaptopurine		<input type="checkbox"/> thioguanine	
Protocol Summaries: (also available on our website <a href="http://www.bccancer.bc.ca">www.bccancer.bc.ca</a> )				<u>Index of Protocol Summaries</u>	
<input type="checkbox"/> BRAJACT	<input type="checkbox"/> BRAJACTG	<input type="checkbox"/> BRAJCEF	<input type="checkbox"/> BRAJCEFG	<input type="checkbox"/> BRAJFEC	<input type="checkbox"/> BRAVDOC
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Pre-printed Orders: (also available on our website <a href="http://www.bccancer.bc.ca">www.bccancer.bc.ca</a> )				<u>Index of Pre-Printed Orders</u>	
<input type="checkbox"/> BRAJACT	<input type="checkbox"/> BRAJACTG	<input type="checkbox"/> BRAVDOC	<input type="checkbox"/> BRAVTAX	<input type="checkbox"/> BRAVTPC	<input type="checkbox"/> BRAVTRAP
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<u>Provincial Systemic Therapy Program Policies</u>					
<u>Reimbursement</u> (also available on our website <a href="http://www.bccancer.bc.ca">www.bccancer.bc.ca</a> )					
<input type="checkbox"/> <u>Benefit Drug List</u> (01 June 2005)			<input type="checkbox"/> <u>Class 2 Form</u> (01 June 2005)		
<u>Systemic Therapy Update Index</u> (also available on our website <a href="http://www.bccancer.bc.ca">www.bccancer.bc.ca</a> )					
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