BC Cancer Agency

Systemic Therapy Update

Volume 6, Number 6 *for health professionals who care for cancer patients* June 2003
Available on website www.bccancer.bc.ca

FEATURE TOPIC
IMPORTANT CHANGES IN PACLITAXEL PRICING

A recent Federal Court ruling has led to a change in purchase practice for paclitaxel by the BC Cancer Agency. As a result, the Agency is now purchasing paclitaxel at a cost that is significantly greater than has been historically the case and this has a major impact on the comparability of price between a variety of different chemotherapy drugs. Without the collaboration of our oncologists in the most cost-effective delivery of care, the Agency would be at risk of losses in excess of $250,000/month, which would adversely affect our ability to support future cancer therapies for patients in BC.

The Provincial Systemic Therapy Program has recently sent out an advisory to all medical oncologists in BC with some information regarding the financial impact of some of the therapeutic choices in circumstances where the evidence and clinical judgment would indicate there is equivalent efficacy between different regimens.

For an indeterminate period, the price comparisons for a three-week cycle for the standard doses of these various agents are as follows:

- *docetaxel*: less than 2/3 of the price of paclitaxel
- *vinorelbine*: approximately 1/10 of the price of paclitaxel
- *gemcitabine*: approximately 1/3 of the price of paclitaxel
- *topotecan*: approximately ½ of the price of paclitaxel

The considered judgement by the physicians for optimal therapy is obviously the primary concern; however, in therapeutically equivalent situations, careful consideration of cost effectiveness will in the long run be in the best interests of all our patients and will be very important in protecting the Agency's drug budget to support access to additional new and effective therapies.

INSIDE THIS ISSUE

HIGHLIGHTS OF PROTOCOL CHANGES

New Protocol for Gynaecological Cancers The use of **vinorelbine** in selected patients with recurrent or progressing epithelial ovarian, fallopian tube or primary peritoneal cancer has been formalised in a new protocol (*U*GOOVVIN). Note that an *Undesignated Indication* application must be completed and submitted to the Provincial Systemic Therapy Program before the drug will be dispensed at a regional cancer centre or reimbursed to a community hospital.

Deleted Protocols for Melanoma Three treatment protocols for malignant melanoma have been deleted due to their low utilisation. These are the adjuvant use of **levamisole** for high risk patients (SMAJLEV), and the combination regimens of **cisplatin** and **dacarbazine** (SMDD) and **tamoxifen** and **vinblastine** (SMTV) for metastatic melanoma.

Revised Protocols Several protocols for **gynaecological** cancers have been revised regarding the preparation of hydration fluid containing **potassium chloride** (GOCXADV, GOSMCC2, GOTDLR). This is to ensure medication safety and is based on international recommendations to remove concentrated potassium chloride vials from the hospital units and replacing them with pre-mixed minibags containing potassium chloride. **Lung** protocols based on combined **cisplatin** and **etoposide** treatment have been revised with the elimination of specified sequence in the administration of the drugs (LUALTL, LUPAVESE, LUPAVESL, LUPE, LUPESL). **Lymphoma** protocols that employ oral **prednisone** have been revised with additional instruction to take the drug with food in a.m. (LYCCOP, LYCHOP, LYCHOP-R, LYCVP, LYODBEP). Finally, the **head and neck** protocol of using **amifostine** as a radio-protective agent has been revised (HNRAMI) to include assessment and precautions on skin reactions in response to recent alert from Health Canada.

BENEFIT DRUG LIST

The current Benefit Drug List, Class II forms and Undesignated Indication Application forms are available on the BC Cancer Agency website (www.bccancer.bc.ca) under Health Professionals Info, Chemotherapy Protocols, Frequently Used Forms.

LIST OF NEW AND REVISED PROTOCOLS

INDEX to BC Cancer Agency Protocol Summaries revised monthly (include tumour group, protocol code, indication, drugs, last revision date and version). Protocol codes for treatments requiring "Undesignated Indication" approval prior to use are prefixed with the letter **U**.

- **BMTMM0301** revised (dose reduction for renal impairment, melphalan administration guideline, potassium chloride in hydration fluid): Conditioning therapy for autologous stem cell transplant using high dose melphalan in the treatment of multiple myeloma
- **BRAVDOC7** revised (hepatic dysfunction table clarified): Palliative therapy for metastatic breast cancer using weekly docetaxel (Taxotere®)
- **CNTEMOZ** revised (Class II form requirement clarified): Therapy for malignant brain tumours using temozolomide
- **GOCXADV** revised (potassium chloride in hydration fluid): Treatment advanced/recurrent non-small cell cancer of the cervix with cisplatin and etoposide
- **GOOVGEM** revised (creatinine tests, dosing modifications): Palliative chemotherapy for re-treatment of ovarian, tubal, and peritoneal cancer using gemcitabine
- **UGOOVVIN** new: Palliative chemotherapy for re-treatment of ovarian, tubal, and peritoneal cancer using vinorelbine
- **GOSMCC2** revised (potassium chloride in hydration fluid): Treatment of small cell carcinoma of cervix using paclitaxel, cisplatin, etoposide and carboplatin with radiation (GO 95 02)
- **GOTDLR** revised (potassium chloride in hydration fluid): Therapy for low risk gestational trophoblastic cancer using dactinomycin and methotrexate
- **GUMVAC** revised (contact physician): Therapy for transitional cell cancers of the urothelium using methotrexate, vinblastine, doxorubicin and cisplatin
- **GUPLHRH** revised (details on side effects): Therapy for prostate cancer using LHRH agonist (goserelin, leuprolide or buserelin)
- **GUPM** revised (Tests and administration guidelines clarified): Therapy for hormone-

resistant metastatic carcinoma of the prostate using mitomycin monotherapy (Standard)

- **GUSCPE** revised (cisplatin and etoposide administration sequence): Therapy of genitourinary small cell tumours with a platin and etoposide
- **HNRAMI** revised (assessment and precautions for skin reactions): Radioprotection in head and neck radiation using amifostine
- **LUALTL** revised (cisplatin and etoposide administration sequence): Therapy for limited stage SCLC using alternating CAV/EP plus early thoracic irradiation using cyclophosphamide, doxorubicin, vincristine, etoposide and cisplatin
- **LUPAVESE** revised (cisplatin and etoposide administration sequence): Treatment For extensive stage small cell lung cancer (SCLC) with cisplatin, doxorubicin, vincristine and etoposide (PAVE)
- **LUPAVESL** revised (cisplatin and etoposide administration sequence): Treatment For limited stage small cell lung cancer (SCLC) with cisplatin, doxorubicin, vincristine and etoposide (PAVE), and cisplatin and etoposide (EP) concurrent with early thoracic irradiation
- **LUPE** revised (cisplatin and etoposide administration sequence): Palliative therapy of selected solid tumours using cisplatin and etoposide
- **LUPESL** revised (cisplatin and etoposide administration sequence): Treatment for limited stage small cell lung cancer (SCLC) with etoposide and cisplatin (EP) and early thoracic irradiation
- **LYCCOP** revised (prednisone administration): Treatment of Hodgkin's lymphoma using cyclophosphamide, vincristine and prednisone
- **LYCHOP** revised (prednisone administration): Treatment of lymphoma with doxorubicin, cyclophosphamide, vincristine and prednisone (CHOP)
- **LYCHOP-R** revised (prednisone administration): Treatment of lymphoma with doxorubicin, cyclophosphamide, vincristine, prednisone and rituximab (CHOP-R)
- **LYCVP** revised (prednisone administration): Treatment of advanced indolent lymphoma using cyclophosphamide, vincristine, prednisone (CVP)
- **LYODBEP** revised (prednisone administration): Treatment of Hodgkin's disease with vincristine, doxorubicin, bleomycin, etoposide and prednisone
- **LYSNCC** revised (cyclophosphamide preparation): Treatment of Burkitt lymphoma with cyclophosphamide and methotrexate
- **PUM** revised (antiemetics premedications): Monotherapy for metastatic carcinomas of unknown primary using mitomycin
- **SAIME** revised (tests, treatment schema, use of etoposide for renal toxicity clarified): Etoposide, ifosfamide-mesna for patients with newly diagnosed Ewing's sarcoma/peripheral neuroectodermal tumor (PNET) or rhabdomyosarcoma or advanced soft tissue or bony sarcomas
- **SMAJLEV** deleted: Adjuvant therapy for high risk malignant melanoma patients using levamisole
- **SMCCNU** revised (contact physician): Second line treatment for metastatic malignant melanoma using lomustine (CCNU)
- **SMDD** deleted: Phase II study of cisplatin and DTIC in patients with metastatic incurable malignant melanoma
- **SMTAM** revised (contact physician): Therapy for malignant melanoma using tamoxifen
- **SMTV** deleted: Second line treatment of metastatic malignant melanoma using tamoxifen and vinblastine

Protocols are available on the BC Cancer Agency website (www.bccancer.bc.ca) under Health Professionals Info, Chemotherapy Protocols.

CANCER MANAGEMENT MANUAL

The Cancer Management Manual is available on the BC Cancer Agency website (www.bccancer.bc.ca) under Health Professionals Info, Cancer Management Guidelines.

PRE-PRINTED ORDER UPDATE

Pre-printed orders should always be checked with the most current BC Cancer Agency protocol summaries. The BC Cancer Agency Vancouver Centre has prepared chemotherapy pre-printed orders, which can be used as a guide for reference. An index to the orders can be obtained by Fax-back.

- **BMTMM0301** revised (potassium chloride in hydration fluid): Conditioning therapy for

autologous stem cell transplant using high dose melphalan in the treatment of multiple myeloma

- **GIFOLFIRI** revised (fluorouracil dose escalation and appointment time clarified): Palliative combination chemotherapy for metastatic colorectal cancer using irinotecan, fluorouracil and folinic acid (leucovorin)
- **UGIFOLFOX** revised (fluorouracil dose escalation and appointment time clarified): Palliative combination chemotherapy for metastatic colorectal cancer using oxaliplatin, 5-fluorouracil and folinic acid (leucovorin)
- **GIFUA** revised (nursing bookings): Curative combined modality therapy for carcinoma of the anal canal using mitomycin, infusional fluorouracil and radiation therapy.
- **GIFUC** revised (appointments): Palliative chemotherapy for upper gastrointestinal tract cancer (gastric, esophageal, gall bladder carcinoma and cholangiocarcinoma) using infusional fluorouracil and cisplatin
- **GUAVPG** revised (carboplatin/gemcitabine option added): Palliative therapy for urothelial carcinoma using cisplatin and gemcitabine
- **GUPDOC** new: Palliative therapy for metastatic hormone refractory prostate cancer using docetaxel.
- **SAAI** revised (medication administration record added): Therapy for advanced soft tissue sarcoma using doxorubicin, ifosfamide-mesna

Patient Education

Patient information handouts for cancer drugs are available on the BC Cancer Agency website (www.bccancer.bc.ca) under Health Professionals Info, Drug Database, Drug Information for the Patient. For treatment protocol specific information, go to the BC Cancer Agency website (www.bccancer.bc.ca) under Health Professionals Info, Chemotherapy Protocols, Information for the Patient.

Cancer Drug Manual

The Cancer Drug Manual is available on the BC Cancer Agency website www.bccancer.bc.ca/cdm/.

Provincial Systemic Therapy Program Policies

BC Cancer Agency Systemic Therapy Policies are available on the BC Cancer Agency website (www.bccancer.bc.ca) under Health Professionals Info, Chemotherapy Protocols, Policies and Procedures.

Focus on Thyrotropin Alfa (Thyrogen ®)

Thyrotropin alpha is a recombinant form of human thyroid stimulating hormone (TSH), used as part of a diagnostic procedure in the follow-up care of patients with thyroid cancer. Following thyroid cancer surgery, patients are usually placed on thyroid hormone therapy to suppress the secretion of TSH, which may stimulate tumour recurrence. Patients are monitored for recurrence by radioiodine scanning. Traditionally, this requires the discontinuation of thyroid hormone therapy to allow the TSH to rise, and stimulate uptake of the radioiodine into any tumour deposits. As a consequence of discontinuing thyroid hormone therapy, some patients may experience severe symptoms of hypothyroidism, such at tiredness and weight gain, as well as dysphoric mood disturbances. For these patients, a more preferable option would be to administer thyrotropin alpha. Thyrotropin alpha can stimulate the uptake of radioactive iodine into any remaining normal thyroid tissue or thyroid carcinoma, without going through thyroid withdrawal.

Effective February 2003, Thyrotropin has been added to the BC Cancer Agency Benefit Drug list as a Class II drug, protocol HNTSH. Patients who are eligible for this protocol are:

- Patients with thyroid cancer who have had either radioactive iodine ablation of post-operative thyroid remnants or treatment of metastatic disease.
- Patients who are not being prepared for radioactive iodine therapy
- Patients who experienced significant morbidity after thyroxine withdrawal in the past
- Patients who are unable to mount an adequate endogenous TSH response to thyroid hormone withdrawal (eg, hypopituitarism)

Patients must be informed that this may be a less effective preparation for iodine scanning than thyroxine withdrawal, but offers an alternative to those who are unable to tolerate the withdrawal process.

Thyrotropin is commercially available as Thyrogen ® and is manufactured by Genzyme. It is distributed through Lynden International Logistics, located in Ontario. (1-800-268-4937) Please note that this product requires refrigeration, and

therefore, the distributor will not send it out on Fridays. Thyrotropin is supplied as a kit, containing two 1.1-mg vials of thyrotropin powder, resulting in a 0.9mg/mL solution per vial after reconstitution.

Thyrotropin is administered as a series of two 0.9-mg intramuscular injections, given 24 hours apart. Twenty-four hours after the last thyrotropin injection, the patient receives a radioiodine drink in preparation for iodine scanning. The scan is performed 48 hours after the radioactive iodine is administered (ie, 72 hours after the last thyrotropin injection).

The most common adverse reactions reported in clinical trials have been nausea (10.5%), headache (7.3%), asthenia (3.4%) and vomiting (2.1%). Hypersensitivity reactions have included urticaria, rash, pruritus and flushing. Caution should also be used in patients with a history of heart disease. Thyrotropin can cause a transient rise in serum thyroid hormone concentration, which can exacerbate existing cardiac conditions, although this is unlikely when any residual thyroid tissue has already been ablated by radioactive iodine.

In conclusion, thyrotropin is an effective alternative to thyroid hormone withdrawal therapy prior to radioiodine scanning, in select patients. At the BC Cancer Agency, the cost of thyrotropin is fully reimbursed through the Systemic Therapy program, as long as the patient meets the requirements as indicated on the HNTSH protocol. A Class II form must be completed with the appropriate indication checked off and should accompany the chemotherapy order. This form must be submitted to the Systemic Therapy program for reimbursement eligibility.

For questions regarding this protocol, please contact Dr. John Hay or tumour designate at 604-877-6000. For questions regarding the reimbursement process, please contact Francis Hu, CON pharmacist at 604-877-6277.

Submitted by,
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References

1. Ladenson PW, Braverman LE, Mazzaferri EL et al. Comparison of administration of recombinant human thyrotropin with withdrawal of thyroid hormone for radioactive iodine scanning in patients with thyroid carcinoma. N Engl J Med 1997;337:888-96.
2. BC Cancer Agency Head & Neck Tumour Group protocol-HNTSH. BCCA protocol summary for radioiodine imaging in patients with thyroid cancer using thyrotropin alpha. Vancouver, British Columbia: BC Cancer Agency; 01 February 2003.
3. Genzyme Canada, Thyrogen ® (thyrotropin alfa) product monograph, May 2002.
4. BC Cancer Agency, Parenteral Drug Manual Monograph. Thyrotropin alpha. 19 April 2001.

LIBRARY/CANCER INFORMATION CENTRE

Unconventional Cancer Therapies Manual is available on the BC Cancer Agency website www.bccancer.bc.ca under Patient/Public Info, Unconventional Therapies. The manual consists of 46 short monographs on the more commonly used unconventional cancer therapies (e.g., Essiac, vitamins, teas, shark cartilage) and includes tips for the patient and family on how unconventional therapies can be evaluated. For each therapy the manual provides proponent/advocate claims, as well as evidence-based evaluation/critique quotations from the literature.

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BULLETIN UPDATES		LOCATION	
Cancer Drug Manual		H:\everyone\systemic\chemo\cancer drug manual monographs	
Pre-Printed Orders		H:\everyone\systemic\chemo\Orders\VCC	
BMTMM0301	UGIFOLFOX	GIFUC	GUPDOC
GIFOLFIRI	GIFUA	GUAVPG	SAAI
Protocol Summaries		H:\everyone\systemic\chemo\Protocol\"tumour site"	
Index of Protocol Summaries		Index_NT or Index_W6	
BMTMM0301	GOTDLR	LUPAVESE	LYCVP
BRAVDOC7	GUMVAC	LUPAVESL	LYODBEP
CNTEMOZ	GUPLHRH	LUPE	LYSNCC
GOCXADV	GUPM	LUPESL	PUM
GOOVGEM	GUSCPE	LYCCOP	SAIME
UGOOVVIN	HNRAMI	LYCHOP	SMCCNU
GOSMMC2	LUALTL	LYCHOP-R	SMTAM
Patient Education Handout		H:\everyone\systemic\chemo\Pt Education	
Provincial Systemic Therapy Policies		H:\everyone\systemic\chemo\policies	
Reimbursement		H:\everyone\systemic\chemo\Reimburs	
Benefit Drug List (June 03)		BenefitList.doc	
Class 2 Form (March 03)		Class2.doc	

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