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

EDITOR'S CHOICE**ADJUVANT AROMATASE INHIBITOR THERAPY FOR BREAST CANCER – NEW POLICY**

A new BCCA policy has been introduced to define the role of *aromatase inhibitors (AI) therapy* (anastrozole, letrozole, exemestane) for adjuvant hormonal management of ER+ **breast cancer**. This is a rapidly evolving area and the policy may change with longer term follow-up of studies (e.g., ATAC, IES, MA17, BIG 1-98), and longer follow-up study of information from the BC Cancer Agency Breast Outcomes Database. In the interim, women with ER+ breast cancer should be managed as follows:

Premenopausal:

Tamoxifen for 5 years (BRAJTAM), unless become post-menopausal during therapy (no menses > 12 months and FSH/LH in postmenopausal range) – then see strategy C below.

Postmenopausal:

Strategy A: Low grade T1N0 tumours should be treated with Tamoxifen monotherapy (BRAJTAM) for 5 years. Substitution of AI is allowed if intolerant or if serious complications or contraindications exist.

Strategy B: Patients with high risk for early relapse should be treated with AI monotherapy for 5 years (BRAJANAS, BRAJEXE, BRAJLET). High risk is defined as:

- High grade, *or*
- Low ER (1+), *or*
- Stage III (Includes any N2/N3, T4, or T3N+)

PR status and her2neu status will also be analyzed in the near future. If appropriate, an update will be issued to indicate whether these factors should affect treatment selection.

Strategy C: All other tumours should be managed with sequential therapy of Tamoxifen followed by AI (BRAJANAS, BRAJEXE, BRAJLET). This may be accomplished by either:

- “Early switch”: Tamoxifen for 2-3 years followed by AI for 3-2 years, for total 5 years of hormone therapy, or
- “Late switch”: Tamoxifen for 5 years followed by AI for 3 years. This is particularly relevant for women who have already finished > 3 years of tamoxifen at the time of this policy change, or who become postmenopausal AFTER completing 3 years of tamoxifen.

The optimal strategy has not yet been determined in this area, particularly the optimal duration of an AI, relative superiority of individual AI agents or of sequential vs. monotherapy. It is anticipated that the sequential approach, with early switch to AI at 2-3 years, will be the predominant strategy for most postmenopausal women. The strategy of a sequential approach has the theoretical advantages of potentially superiority in overcoming treatment resistance and lower cumulative risks of long-term exposure to either tamoxifen alone or AI alone (less AI-related osteoporosis risk, and tamoxifen-related uterine malignancy and thrombosis risk). For those women completing adjuvant chemotherapy with loss of menses during therapy, upfront use of tamoxifen allows hormone therapy to proceed while the impact of adjuvant chemotherapy on ongoing menstrual status is determined.

These treatment policies will be analysed and updated further as additional information evolves over the next 5 years.

ADJUVANT CAPECITABINE FOR COLON CANCER

The *Gastrointestinal Tumour Group* has introduced a new adjuvant regimen for high-risk *resected colon cancer* using the oral agent *capecitabine* (GIAJCAP). Traditionally, *5-fluorouracil* (5FU) has been the mainstay of adjuvant therapy in this population (stage III, high risk stage II). The most commonly used regimen in Canada being the so-called Mayo regimen of bolus 5FU and leucovorin (LV) (GIFFAD protocol). Oral capecitabine offers the potential advantages of ease of administration, improving access to care in remote settings, and the removal of the requirement for central venous access, with the attendant risks (hemorrhage, thrombosis, infection) and inconvenience (dressing changes, line flushing, cosmetic issues.)

There is preliminary direct evidence to support the use of capecitabine as an alternative to bolus 5FU/LV as adjuvant therapy of colon cancer. A recent randomized trial has shown equivalent 3-year disease free and overall survival in patients with stage III resected colon cancer. Additionally, several problematic 5FU toxicities were significantly reduced in incidence and/or severity with capecitabine, supporting capecitabine’s better safety profile, although the mortality rate with either regimen was the same.

NEW AND REVISED PROTOCOLS FOR METASTATIC BREAST CANCER

The *Breast Tumour Group* has introduced a new treatment of HER-2/neu positive metastatic breast cancer using *docetaxel* and *trastuzumab* (BRAVTRAD). This program may be preferred over the existing paclitaxel and trastuzumab combination (BRAVTPC) for some patients due to toxicity or convenience issues. The BRAVTPC or BRAVTRAD protocols would generally be the preferred regimens for first line therapy of metastatic HER-2/neu positive breast cancer, unless toxicity concerns, prior therapy history, or other considerations dictate the use of other trastuzumab-containing regimens.

Other major changes include the deletion of *prior treatment with anthracyclines* from the eligibility criteria of *trastuzumab*-based protocols (BRAVTPC, BRAVTR, BRAVTRAP, BRAVTRNAV) for patients with her2neu+ metastatic breast cancer. This has several practical advantages, including:

- a better chance of response and possibly enhanced survival
- a better toxicity profile
- the ability to offer maintenance trastuzumab after response to improve time to progression, and
- avoiding anthracyclines-related cardiac toxicity which may hinder future ability to receive trastuzumab safely.

BENEFIT DRUG LIST

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

<i>Drug</i>	<i>Indication</i>	<i>Benefit status</i>
Anastrozole	adjuvant aromatase inhibitor (AI) therapy for breast cancer (BRAJANAS)	added as Class I
Capecitabine	adjuvant therapy of colon cancer using capecitabine (GIAJCAP)	added as Class II
Docetaxel	treatment of HER-2/neu positive metastatic breast cancer using docetaxel and trastuzumab (BRAVTRAD)	added as Class II
Exemestane	adjuvant aromatase inhibitor (AI) therapy for breast cancer (BRAJEXE)	added as Class I
Letrozole	adjuvant aromatase inhibitor (AI) therapy for breast cancer (BRAJLET)	added as Class I
Trastuzumab	Treatment of HER-2/neu positive metastatic breast cancer using docetaxel and trastuzumab (BRAVTRAD)	added as Class II

DRUG UPDATE

Etoposide Oral Solution The etoposide monograph of the Cancer Drug Manual was recently completely revised. An important change found in the new revision is the management of patients that are unable to swallow etoposide capsules. Previously, these patients were advised to pierce the capsule and squeeze the contents into water. The new practice is now to prepare an oral solution for these patients using Vepesid® injection.

Problems with the previous practice of piercing the capsules were identified by the manufacturer.¹ Upon dilution of the liquid from the capsule into water, etoposide can precipitate out of solution. The implications of this precipitation for drug efficacy are unknown. In addition, it is not possible to estimate the amount of drug that is received by the patient. The liquid in the capsule is viscous, and will adhere to the capsule shell and anything else with which it comes into contact.

The use of Vepesid® injection to prepare an oral solution is well supported, as is the formulation and stability information.¹⁻⁷ The injection is diluted with normal saline to 10 mg/mL and stored in 5 mL oral syringes or in an amber glass bottle. The prepared solution is stable for 22 days at room temperature. The solution can be further diluted immediately prior to administration in apple, orange or lemon juice (**not grapefruit juice**). The final concentration should be ≤ 0.4 mg/mL to enhance the taste (eg, dilute 50 mg [5 mL] oral solution to at least 125 mL fruit juice). At higher concentrations in fruit juice, precipitation may occur in less than 3 hours. There is no significant difference in bioavailability between taking the capsule and drinking the injection.

This change may result in an increased workload. However, in light of the available information, preparation of an oral solution using Vepesid® injection is the preferred practice in the management of patients who are unable to swallow etoposide capsules.

Submitted by:

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References:

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2. Calgary Health Region. Compounded Drug Formulas Etoposide 10 mg/mL oral solution. 2002.
3. Healthcare MR. DRUGDEX DRUG EVALUATIONS Etoposide; 2005.
4. Roberta Esau. Personal communication. Pharmacist, British Columbia Children's Hospital, Oncology/Hematology Clinic 2005.
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FOCUS ON BACILLUS CALMETTE-GUERIN (BCG)

Bacillus Calmette-Guerin (BCG) is a live, attenuated mycobacterium. It has been used as a vaccine against tuberculosis. However in the oncology setting, it is used in the treatment of bladder cancer. The exact mechanism of this activity is unknown but it is believed that BCG administered intravesically may cause an inflammation in the lining of the bladder. This inflammation stimulates an immune response against the disease.

BCG should not be used in patients with impaired immune response, patients who are HIV positive or in patients with an active tuberculosis infection.

At the BC Cancer Agency, BCG is used in two bladder protocols:

- GUBCG is the protocol summary for high risk superficial transitional cell bladder cancer using BCG. It provides guidelines for the consulting urologist, and is to be used in conjunction with the BCCA Cancer Management Guidelines.
- GUBCGIFN is the protocol summary for palliative therapy for BCG-refractory superficial high-grade transitional cell carcinoma bladder with BCG and Interferon.

In both protocols, the BCG dose is diluted and administered directly into the bladder (intravesical). More details can be found in the GUBCG protocol.

Adverse effects are usually localized to the bladder (generally only experienced when BCG is used as a single agent due to the higher dose used) and include: dysuria, urinary frequency and cystitis (40-50%). Hematuria can also be expected (40%). Irritative side effects can be managed symptomatically with phenazopyridine, propantheline or acetaminophen. or dosage reduction - see protocol for guidelines. There are generally no long-term urinary complications. Systemic adverse effects can include flu-like symptoms, including fever and malaise/fatigue. This can be managed with bed rest and antipyretics.

BCG for treatment in bladder cancer is available commercially as ImmuCyst® (Connaught substrain), manufactured by Aventis Pasteur and OncoTICE® (TICE substrain), manufactured by Organon. Both products are recommended for intravesical use only and considered interchangeable at the following dosage:

ImmuCyst® 81 mg = OncoTICE® 50 mg vial

Handling precautions

BCG contains live, attenuated bacteria, which presents a potential risk for transmission so must be handled as a biohazard material. Persons handling BCG should wear proper protective equipment, including a mask and gloves. All disposable equipment and materials used for preparation and administration should be considered biohazard waste.

The manufacturers of OncoTICE® have produced a BCG Reconstitution Kit® which is distributed by Mayne Pharma (Canada). This kit provides for a means of reconstituting and administering the drug within a closed system.

In summary, BCG has a role in the treatment of bladder cancer. As it contains live attenuated bacteria, it should be handled cautiously.

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Bibliography:

1. BCCA Protocol GUBCG (BCCA Protocol Summary for BCG Therapy in Bladder Cancer) Vancouver: BC Cancer Agency (2000 December 01).
2. BCCA Protocol GUIFBCG (BCCA Protocol Summary for BCG-refractory superficial high-grade TCC with BCG and Interferon) Vancouver: BC Cancer Agency (2005 March)
3. de Lemos, ML, editor. BCG Monograph, BC Cancer Agency Cancer Drug Manual. Vancouver: BC Cancer Agency, 2005 January 01.
4. ImmuCyst ® monograph, Compendium of Pharmaceutical and Specialties, 2004. Ottawa: Canadian Pharmaceutical Association.
5. Mayne Pharma, Canada Inc. BCG Reconstitution Kit. Kirkland Quebec; Mayne Pharma; February 2004.
6. Mayne Pharma, Canada Inc. OncoTice ® Patient Information Booklet. Canada. 2003 September.
7. OncoTice ® monograph, Compendium of Pharmaceutical and Specialties, 2004. Ottawa: Canadian Pharmaceutical Association

NURSING UPDATE

Webcast is a live video session that is filmed and available to you one line, free. The following 3 webcasts have already been presented by CANO and are therefore archived in their website. You can view any of these presentations by linking with the website below, selecting the program and pressing the “play” button:

<http://www.cos.ca/cano/web/en/index.html>

You will need internet access with speakers to view these. Most programs run for 30-45 minutes.

- *CANO Pain Resource: How to Best Advocate for Our Patients and Their Pain Control*
- *Anemia & Fatigue: More than just "pale" and "tired"*
Cancer and Weight Loss: what we know and what we can do.
- *Lesson from the Cancer Wars. Improving communication between patients and health care professionals.*

CANCER DRUG MANUAL

Paclitaxel Monograph has been revised to clarify the dosing in patients with hepatic insufficiency and in pediatric patients. Paclitaxel is hepatically metabolized and excreted, putting patients with hepatic insufficiency at higher risk of myelosuppression and other toxicities. The previous monograph does not provide dosing guidelines in all situations, as some patients do not fit into any of the defined groups. This latest revision should ensure a recommendation for all patients. The guidelines are based on those found in the U.S. product monograph (package insert); these have been confirmed by an independent literature review by the Cancer Drug Manual pharmacists. It should be noted that these recommendations are based on a 3-hour infusion of paclitaxel, and are suggestions for the first dose only. Subsequent doses should be based on patient tolerance and clinical judgment. Information on hepatic dosing of paclitaxel is not currently available in the Canadian package insert, but the manufacturer reports that an update is underway.

For pediatric patients, the paclitaxel dose has been verified and pediatric doses of pre-medications have been added.

Thiotepa Monograph and Patient Information have been revised to include information on the intrathecal route of administration. This route has not been approved by Health Canada, but is occasionally used for patients with leptomeningeal metastases from solid tumours. Intrathecal injections must be isotonic, preservative-free, and buffered. A formulation of 1 mg/mL thiotepa in preservative-free sterile water for injection has historically been used for intrathecal administration, based on studies done in the 1970's. Since that time, the formulation of thiotepa has changed from a solution containing sodium chloride and sodium bicarbonate to a lyophilized powder containing only thiotepa. The powder must be reconstituted with 1.5 mL of sterile water to yield a hypotonic solution of 10 mg/mL, which must be further diluted with NS prior to administration. For intrathecal use, BCCA protocols now use 2 mg/mL thiotepa in NS for a more isotonic solution that is physically and chemically stable and is sufficiently concentrated for use with an Ommaya reservoir.

Pamidronate Patient Information has been revised to reflect the manufacturer's warnings concerning the development of osteonecrosis of the jaws. Patients are encouraged to have a dental consultation, ideally with a

specialist in oral medicine, or a member of the Oral Oncology staff at a BC Cancer Agency facility, prior to starting pamidronate therapy. Any necessary preventive dental work should be done before treatment in order to minimize the risk of this occurrence.

Mechlorethamine Patient Information on Topical Solution and Ointment have been revised to emphasise avoiding contact to eyebrows and between the toes.

PATIENT EDUCATION

New Patient Handout on Lymphoma Protocol has been developed for LYCHOPR (CHOP plus rituximab) protocol.

Revised Patient Handouts on Cancer Drugs The patient information handouts for **Pamidronate**, **Mechlorethamine (solution and ointment)** and **Thioguanine** have been revised. See under Cancer Drug Manual for more details.

LIST OF NEW AND REVISED PROTOCOLS

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:

- **BRAJANAS** new: Adjuvant anastrozole for breast cancer
- **BRAJEXE** new: Adjuvant exemestane for breast cancer
- **BRAJLET** new: Adjuvant letrozole for breast cancer
- **BRAVTRAD** new: Treatment of HER-2/neu positive metastatic breast cancer using docetaxel and trastuzumab
- **GIAJCAP** new: Adjuvant treatment of high-risk resected colon cancer using capecitabine (GIAJCAP)

Revised protocols:

- **BRAJACT** revised (*paclitaxel hypersensitivity management added*): Adjuvant therapy for breast cancer using doxorubicin and cyclophosphamide followed by paclitaxel
- **BRAJACTG** revised (*paclitaxel hypersensitivity management added*): Adjuvant therapy for breast cancer using doxorubicin and cyclophosphamide followed by paclitaxel
- **BRAJFEC** revised (*dose modification table clarified*): Adjuvant therapy for breast cancer using fluorouracil, epirubicin and cyclophosphamide.
- **BRAJLETL** deleted (*replaced by BRAJLET*): Adjuvant therapy of letrozole in postmenopausal women after five years of tamoxifen for early breast cancer
- **BRAJTAM** revised (*duration of therapy*): Adjuvant therapy for breast cancer using tamoxifen
- **BRAVTPC** revised (*need for prior anthracyclines deleted from title and eligibility*): Palliative therapy for metastatic breast cancer using trastuzumab (Herceptin®), paclitaxel and carboplatin as first-line treatment for recurrent breast cancer
- **BRAVTR** revised (*need for prior anthracyclines deleted from eligibility*): Palliative therapy for metastatic breast cancer using trastuzumab (Herceptin®)
- **BRAVTRAP** revised (*need for prior anthracyclines and deleted from title and eligibility*): Palliative therapy for metastatic breast cancer using trastuzumab (Herceptin®) and paclitaxel as first-line treatment for recurrent breast cancer
- **BRAVTRNAV** revised (*need for prior anthracyclines deleted from eligibility*): Palliative therapy for metastatic breast cancer using trastuzumab (Herceptin®) and vinorelbine
- **UGICAPOX** revised (*prophylactic calcium and magnesium added*): Palliative combination chemotherapy for metastatic colorectal cancer using oxaliplatin, and capecitabine

- **UGIFOLFOX** revised (prophylactic calcium and magnesium added): Palliative combination chemotherapy for metastatic colorectal cancer using oxaliplatin, 5-fluorouracil and folinic acid (leucovorin)
- **MOIT** revised (*dilution volume clarified*): Therapy for solid tumours using intrathecal methotrexate and/or thiotepa and/or cytarabine

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, non-PVC tubing with in-line filter added*): Adjuvant therapy for breast cancer using doxorubicin and cyclophosphamide followed by paclitaxel
- **BRAJACTG** revised (*non-PVC tubing with in-line filter added*):
- **BRAVTAX** revised (*non-PVC tubing with in-line filter added*): Palliative therapy for metastatic breast cancer using paclitaxel
- **BRAVTPC** revised (*need for prior anthracyclines deleted eligibility*): Palliative therapy for metastatic breast cancer using trastuzumab (Herceptin®), paclitaxel and carboplatin as first-line treatment for recurrent breast cancer
- **BRAVTPC** revised (*non-PVC tubing with in-line filter 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 (*need for prior anthracyclines deleted from eligibility*): Palliative therapy for metastatic breast cancer using trastuzumab (Herceptin®)
- **BRAVTRAP** revised (*need for prior anthracyclines and deleted from eligibility*): Palliative therapy for metastatic breast cancer using trastuzumab (Herceptin®) and paclitaxel as first-line treatment for recurrent breast cancer
- **BRAVTRAP** revised (*non-PVC tubing with in-line filter 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 (*need for prior anthracyclines deleted from eligibility*): Palliative therapy for metastatic breast cancer using trastuzumab (Herceptin®) and vinorelbine
- **GIAJCAP** new: Adjuvant treatment of high-risk resected colon cancer using capecitabine
- **GOCXCAT** revised (*non-PVC tubing with in-line filter added*): Primary treatment of advanced/recurrent non-small cell cancer of the cervix with carboplatin and paclitaxel in ambulatory care settings
- **GOCXCAT** revised (*paclitaxel preparation using non-PVC tubing with in-line filter*): Primary treatment of advanced/recurrent non-small cell cancer of the cervix with carboplatin and paclitaxel in ambulatory care settings
- **GOENDCAT** revised (*non-PVC tubing with in-line filter added*): Treatment of primarily advanced or recurrent endometrial cancer using carboplatin and paclitaxel
- **GOOVCATM** revised (*non-PVC tubing with in-line filter added*): 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 (*non-PVC tubing with in-line filter added*): Second line treatment using paclitaxel and carboplatin for epithelial ovarian cancer relapsing after primary treatment
- **GOOVCATX** revised (*non-PVC tubing with in-line filter added*): Primary treatment of visible residual (extreme risk) invasive epithelial ovarian cancer in ambulatory care settings using paclitaxel and carboplatin
- **GOOVTAX3** revised (*non-PVC tubing with in-line filter added*): Treatment of progressive, platinum-refractory epithelial ovarian carcinoma, primary peritoneal carcinoma or fallopian tube carcinoma using paclitaxel
- **GOSMCC2** revised (*non-PVC tubing with in-line filter added*): Treatment of small cell carcinoma of cervix using paclitaxel, cisplatin, etoposide and carboplatin with radiation
- **UGUTAXGEM** revised (*paclitaxel preparation using non-PVC tubing with in-line filter*): Palliative therapy for germ cell cancers using paclitaxel and gemcitabine

- **HNDE** revised (*return appointment orders clarification of test frequency*): Therapy for recurrent and metastatic nasopharyngeal cancer using cisplatin and etoposide
- **LUAJNP** revised (*day for creatinine clearance clarified*): Adjuvant cisplatin and vinorelbine following resection of stage I, II and IIIA non-small cell lung cancer
- **MOIT** revised (*dilution volume clarified*): Therapy for solid tumours using intrathecal methotrexate and/or thiotepa and/or cytarabine

CONTINUING EDUCATION – MARK YOUR CALENDAR

- **2-5 October 2005:** Annual Canadian Association of Oncology Nursing Conference, Moncton, New Brunswick (www.cos.ca/cano)
- **23-26 October 2005:** 1st International Cancer Control Congress, Pan Pacific Hotel, Vancouver, BC (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 (www.bccancer.bc.ca)

WEBSITE RESOURCES

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/.

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) 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) 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) 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 under Patient/Public Info, Unconventional Therapies.

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<input type="checkbox"/> LYCHOPR Protocol					
Protocol Summaries: (also available on our website www.bccancer.bc.ca)				<u>Index of Protocol Summaries</u>	
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Pre-printed Orders: (available on our website www.bccancer.bc.ca)				<u>Index of Pre-Printed Orders</u>	
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